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Attorneys for Plaintiff Becton, Dickinson and Company

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BECTON, DICKINSON AND COMPANY,	
Plaintiff,	
v.	Civil Action No. ___________
INSULET CORPORATION,	**DEMAND FOR JURY TRIAL**
Defendants.	

COMPLAINT

Plaintiff Becton, Dickinson and Company (“BD”) brings this complaint for patent infringement against Defendant Insulet Corporation (“Insulet”).

NATURE OF ACTION

1. This is an action for patent infringement under 35 U.S.C. § 271, et seq., by BD against Insulet for infringement of United States Patent Nos. 5,536,249 C1 ("the '249 patent"), 5,925,021 ("the '021 patent"), and 5,957,895 ("the '895 patent").

PARTIES

2. Plaintiff BD is a corporation organized and existing under the laws of New Jersey, with a place of business at 1 Becton Drive, Franklin Lakes, New Jersey 07417-1880. BD is the assignee and owner of the '249, '021, and '895 patents.

3. Upon information and belief, Defendant Insulet Corporation is a corporation organized under the laws of the State of Delaware, with a principal place of business at 9 Oak Park Drive, Bedford, Massachusetts 01730.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271, et seq.

5. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338.

6. Upon information and belief, Insulet has voluntarily placed its diabetes management products, including the Omnipod® Insulin Management System, into the stream of commerce, knowing that New Jersey is the likely destination of a substantial quantity of such products.

7. Upon information and belief, a substantial part of the events giving rise to these claims for patent infringement occurred in New Jersey and in this judicial district.

8. Upon information and belief, Insulet is subject to personal jurisdiction in this district because it maintains or has maintained continuous and systematic contacts with New Jersey and this judicial district.

9. Upon information and belief, Insulet is subject to personal jurisdiction in this district because it purposefully engaged in activities that gave rise to BD's claims for patent infringement and which were directed to residents of New Jersey and this judicial district.

10. Upon information and belief, Insulet resides in this district for purposes of 28 U.S.C. §§ 1391(c) and 1400(b) because it is subject to personal jurisdiction in this district.

11. Upon information and belief, venue for this civil action in this judicial district is proper under 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b), as Insulet is subject to personal jurisdiction in this district.

COUNT 1: PATENT INFRINGEMENT OF U.S. PATENT NO. 5,536,249 C1

12. BD incorporates by reference paragraphs 1-11 as if fully set forth herein.

13. On July 16, 1996, the United States Patent and Trademark Office ("PTO") duly and legally issued United States Patent No. 5,536,249, entitled "Pen-Type Injector with a Microprocessor and Blood Characteristic Monitor," to the inventors Thomas P. Castellano and Robert Schumacher. This patent was assigned to Visionary Medical Products, Inc., at the time of issuance. On October 9, 2007, the PTO duly and legally issued Ex Parte Reexamination Certificate No. 5,536,249 C1, having the same title and inventors. Plaintiff BD is the current assignee and owner of the '249 patent, a copy of which is attached as Exhibit A.

14. Upon information and belief, Insulet has infringed and continues to infringe the '249 patent under 35 U.S.C. § 271(a), (b), and/or (c), by making, using, offering for sale, selling, and/or importing into the United States diabetes management systems, including the Omnipod®

Insulin Management System, and by contributing to and/or inducing infringement of the ’249 patent.

15. Insulet does not have a license or permission to use the ’249 patent.

16. As a result of Insulet’s infringement of the ’249 patent, BD has suffered, and continues to suffer, damages, in an amount not yet determined.

17. As a result of Insulet’s infringement of the ’249 patent, BD has been irreparably injured. Unless such infringing acts are enjoined by this Court, BD will continue to suffer additional irreparable injury.

18. In a series of letters, dated September 22, 2009, February 12, 2010, and April 27, 2010, BD provided notice to Insulet of the ’249 patent and its infringing conduct.

19. Despite knowledge of the ’249 patent, Insulet has continued to infringe this patent. Insulet acted with reckless disregard of the ’249 patent by continuing to infringe the patent when it knew or should have known that its actions constituted infringement.

COUNT 2: PATENT INFRINGEMENT OF U.S. PATENT NO. 5,925,021

20. BD incorporates by reference paragraphs 1-11 as if fully set forth herein.

21. On July 20, 1999, the PTO duly and legally issued United States Patent No. 5,925,021, entitled “Medication Delivery Device with a Microprocessor and Characteristic Monitor,” to the inventors Thomas P. Castellano and Robert Schumacher. The ’021 patent was assigned to Visionary Medical Products, Inc., at the time of issuance. Plaintiff BD is the current assignee and owner of the ’021 patent, a copy of which is attached as Exhibit B.

22. Upon information and belief, Insulet has infringed and continues to infringe the ’021 patent under 35 U.S.C. § 271(a), (b), and/or (c), by making, using, offering for sale, selling, and/or importing into the United States diabetes management systems, including the Omnipod®

Insulin Management System, and by contributing to and/or inducing infringement of the ’021 patent.

23. Insulet does not have a license or permission to use the ’021 patent.

24. As a result of Insulet’s infringement of the ’021 patent, BD has suffered, and continues to suffer, damages, in an amount not yet determined.

25. As a result of Insulet’s infringement of the ’021 patent, BD has been irreparably injured. Unless such infringing acts are enjoined by this Court, BD will continue to suffer additional irreparable injury.

COUNT 3: PATENT INFRINGEMENT OF U.S. PATENT NO. 5,957,895

26. BD incorporates by reference paragraphs 1-11 as if fully set forth herein.

27. On September 28, 1999, the PTO duly and legally issued United States Patent No. 5,957,895, entitled “Low-Profile Automatic Injection Device with Self-Emptying Reservoir,” to the inventors Burton H. Sage and Robert I. Connelly. Plaintiff BD is the assignee and owner of the ’895 patent, a copy of which is attached as Exhibit C.

28. Upon information and belief, Insulet has infringed and continues to infringe the ’895 patent under 35 U.S.C. § 271(a), (b), and/or (c), by making, using, offering for sale, selling, and/or importing into the United States diabetes management systems, including the Omnipod® Insulin Management System, and by contributing to and/or inducing infringement of the ’895 patent.

29. Insulet does not have a license or permission to use the ’895 patent.

30. As a result of Insulet’s infringement of the ’895 patent, BD has suffered, and continues to suffer, damages, in an amount not yet determined.

31. As a result of Insulet's infringement of the '895 patent, BD has been irreparably injured. Unless such infringing acts are enjoined by this Court, BD will continue to suffer additional irreparable injury.

PRAYER FOR RELIEF

WHEREFORE, BD respectfully requests the following relief:

(a) a declaration that Insulet infringes each of the ’249, ’021, and ’895 patents under 35 U.S.C. § 271(a), (b), and/or (c), and a final judgment incorporating the same;

(b) equitable relief under 35 U.S.C. § 283, including, but not limited to, an injunction that enjoins Insulet and any of its officers, agents, employees, assigns, representatives, privies, successors, and those acting in concert or participation with them from infringing, contributing to, and/or inducing infringement of the ’249, ’021, and ’895 patents;

(c) an award of damages sufficient to compensate BD for infringement of the ’249, ’021, and ’895 patents by Insulet, together with prejudgment and post-judgment interest under 35 U.S.C. § 284;

(d) entry of an order compelling Insulet to compensate BD for any ongoing and/or future infringement of the ’249, ’021, and ’895 patents, in an amount and under terms appropriate under the circumstances;

(e) a declaration or order finding that Insulet’s infringement is willful and/or an order increasing damages under 35 U.S.C. § 284;

(f) a judgment holding that this is an exceptional case under 35 U.S.C. § 285 and awarding BD its reasonable attorney fees, costs, and expenses; and

(g) such other relief deemed just and proper.

JURY DEMAND

Under Rule 38 of the Federal Rules of Civil Procedure, BD hereby demands trial by jury of all issues so triable by a jury in this action.

Dated: August 25, 2010

Respectfully submitted,

s/John E. Flaherty
John E. Flaherty
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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the above-captioned action is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: August 25, 2010

Respectfully submitted,

s/John E. Flaherty
John E. Flaherty
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EXHIBIT A

US005536249A

United States Patent [19]

Castellano et al.

[11] **Patent Number: 5,536,249**

[45] **Date of Patent: Jul. 16, 1996**

[54] **PEN-TYPE INJECTOR WITH A MICROPROCESSOR AND BLOOD CHARACTERISTIC MONITOR**

[75] Inventors: **Thomas P. Castellano**, Los Angeles; **Robert Schumacher**, Beverly Hills, both of Calif.

[73] Assignee: **Visionary Medical Products, Inc.**, Los Angeles, Calif.

[21] Appl. No.: **208,636**

[22] Filed: **Mar. 9, 1994**

[51] **Int. Cl.**^{6} **A61M 5/10**

[52] **U.S. Cl.** **604/65**; 128/DIG. 1

[58] **Field of Search** .... 604/65, 30–34, 604/66–67, 118, 151, 246, 264, 280; 128/DIG. 1, DIG. 12, DIG. 13

[56] **References Cited**

U.S. PATENT DOCUMENTS

1,997,129	4/1935	Taylor et al. .
2,221,739	11/1940	Reiter .
2,605,763	8/1952	Smoot .
2,632,445	3/1953	Kas .
2,695,023	11/1954	Brown .
2,718,299	9/1955	Atwater et al. .
3,110,310	11/1963	Cislak .
3,141,583	7/1964	Mapel et al. .
3,293,749	12/1966	George et al. .
3,348,545	10/1967	Sarnoff et al. .
3,481,510	12/1969	Allen, Jr. .
3,517,668	6/1970	Brickson .
3,583,399	6/1971	Ritsky .
3,894,663	7/1975	Carhart et al. .
3,977,574	8/1976	Thomas .
4,022,207	5/1977	Citrin .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

1103314	6/1981	Canada .
0037696	10/1981	European Pat. Off. .
0058536	8/1982	European Pat. Off. .
0143895	6/1985	European Pat. Off. .
0416975	3/1991	European Pat. Off. .
91225137	6/1991	European Pat. Off. .
93249687	6/1993	European Pat. Off. .
1149735	12/1957	France .
1170312	1/1959	France .
1445659	6/1966	France .
2418642	9/1979	France .
2557445	5/1985	France .
730971	12/1942	Germany .
1070784	12/1959	Germany .
22140	10/1961	Germany .
293302	9/1953	Switzerland .
1225495	3/1971	United Kingdom .
1574267	9/1980	United Kingdom .
2109690	2/1982	United Kingdom .
WO8502546	6/1985	WIPO .
8601728	3/1986	WIPO .
9213583	8/1992	WIPO .

OTHER PUBLICATIONS

Search Report for PCT/US95/02727, mailed Jun. 20, 1995, case claims priority on this U.S. application.

Annual International Conference of the IEEE Engineering in Medicine and Biology Society, "An Optical and RF Telemetry Drug Injection Control and ECG System for Awake Small Animal Studies", vol. 13, No. 5, 1991.

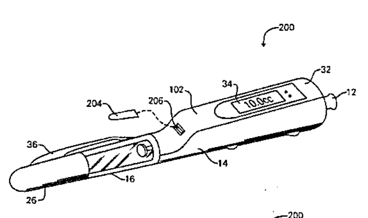
PCT Written Opinion issued by the European Patent Office on Nov. 3, 1995.

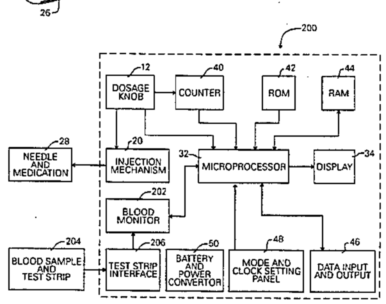
Primary Examiner—Manuel Mendez
Attorney, Agent, or Firm—Loeb & Loeb

[57] **ABSTRACT**

A medical injection device, such as a pen-type injector has a microprocessor coupled to the injector that records the date, the time, and the amount of each injection. The microprocessor may also be coupled to a display to indicate the amount of medication to be injected. The medical injection device can also be coupled with a blood characteristic monitor to analyze characteristics of the blood. This provides a single, all-in-one device that performs a variety of functions, and requires only a minimum of space. The medical injection device may also use a disposable needle that substantially eliminates or reduces bleeding from an opening in the skin at the injection site.

55 Claims, 19 Drawing Sheets





U.S. PATENT DOCUMENTS

4,099,548	7/1978	Sturm et al. .	
4,146,029	3/1979	Ellinwood, Jr.	128/260
4,333,458	6/1982	Margulies et al. .	
4,395,921	8/1983	Oppenlander .	
4,413,760	11/1983	Paton .	
4,415,101	11/1983	Shapiro et al. .	
4,425,121	1/1984	Young et al. .	
4,435,173	3/1984	Siposs et al.	128/DIG. 1
4,444,560	4/1984	Jacklich .	
4,457,712	7/1984	Dragan .	
4,470,317	9/1984	Sabloewski et al. .	
4,475,905	10/1984	Himmelstrup .	
4,498,904	2/1985	Turner et al. .	
4,526,294	7/1985	Hirschmann et al. .	
4,529,401	7/1985	Uslie et al.	128/DIG. 1
4,581,022	4/1986	Leonard et al. .	
4,592,745	6/1986	Rex et al.	604/211
4,659,327	4/1987	Bennett et al. .	
4,664,128	5/1987	Lee .	
4,710,172	12/1987	Jacklich et al. .	
4,710,178	12/1987	Leonard et al. .	
4,820,287	4/1989	Leonard .	
4,865,591	9/1989	Sams .	
4,883,472	11/1989	Michel	604/208
4,936,833	6/1990	Sams	604/232
4,950,246	8/1990	Muller	604/154
4,959,056	9/1990	Dombrowski et al.	604/186
4,998,570	3/1991	Strong	128/DIG. 1
5,024,656	6/1991	Gasaway et al.	604/70
5,069,668	12/1991	Boydman	604/121
5,085,642	2/1992	Sarnoff et al.	604/134
5,092,842	3/1992	Bechtold et al.	604/135
5,102,393	4/1992	Sarnoff et al.	604/136
5,104,380	4/1992	Holman et al.	604/117
5,112,317	5/1992	Michel	604/208
5,114,406	5/1992	Gabriel et al.	604/136
5,139,484	8/1992	Hazon et al.	128/DIG. 1
5,180,371	1/1993	Spinallo	604/207
5,226,895	7/1993	Harris	604/208
5,226,896	7/1993	Harris	604/211
5,244,461	9/1993	Derlien	128/DIG. 1
5,244,465	9/1993	Michel	604/208
5,279,585	1/1994	Balkwill	604/207
5,279,586	1/1994	Balkwill	604/207
5,383,865	1/1995	Michel	604/208

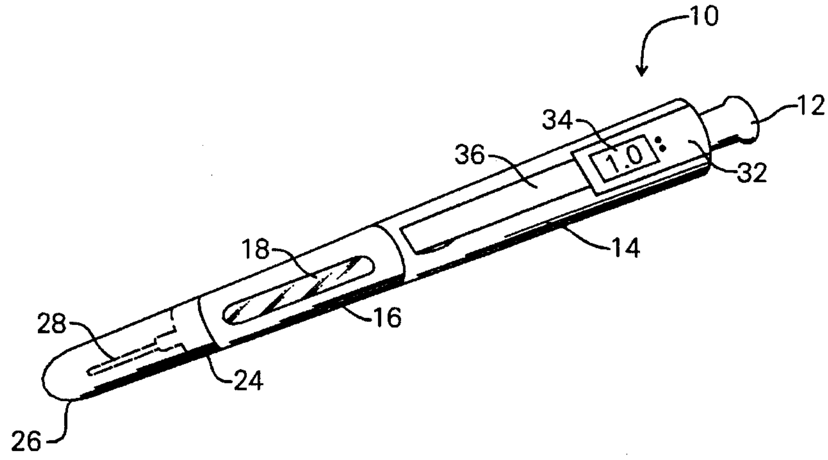

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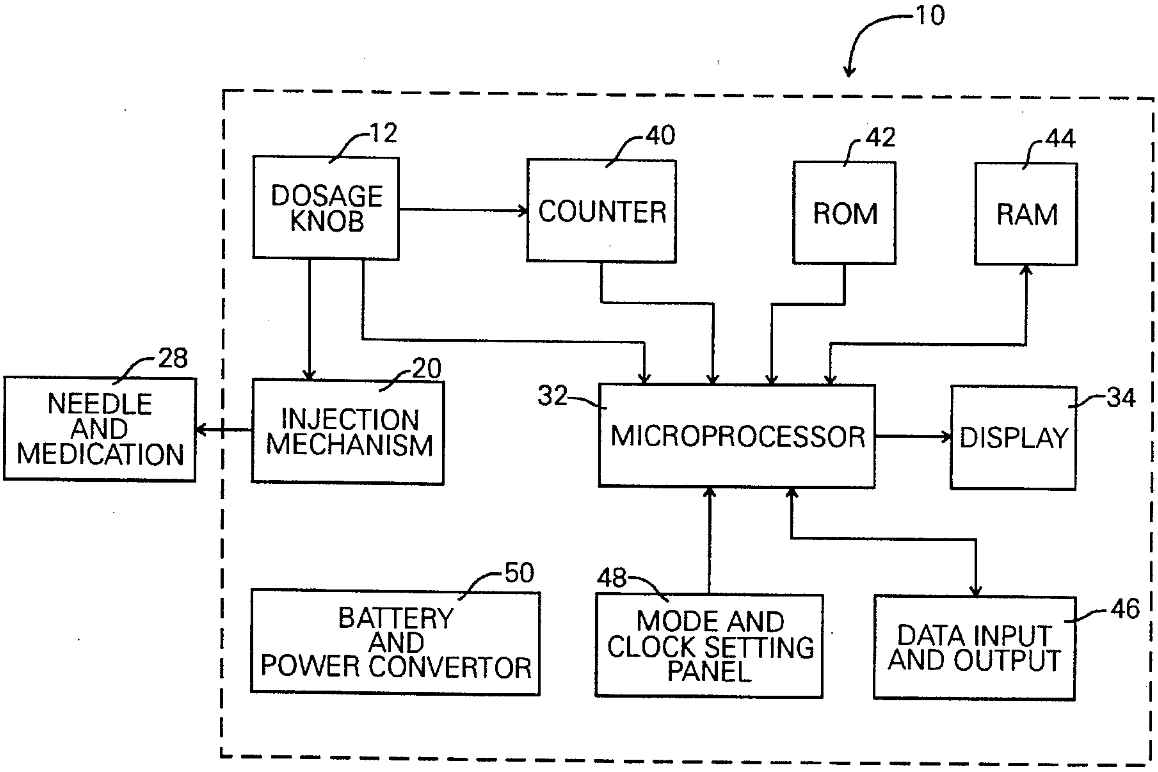
FIG. 1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BATTERY AND POWER CONVERTOR
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MODE AND CLOCK SETTING PANEL
DATA INPUT AND OUTPUT
46

FIG. 4

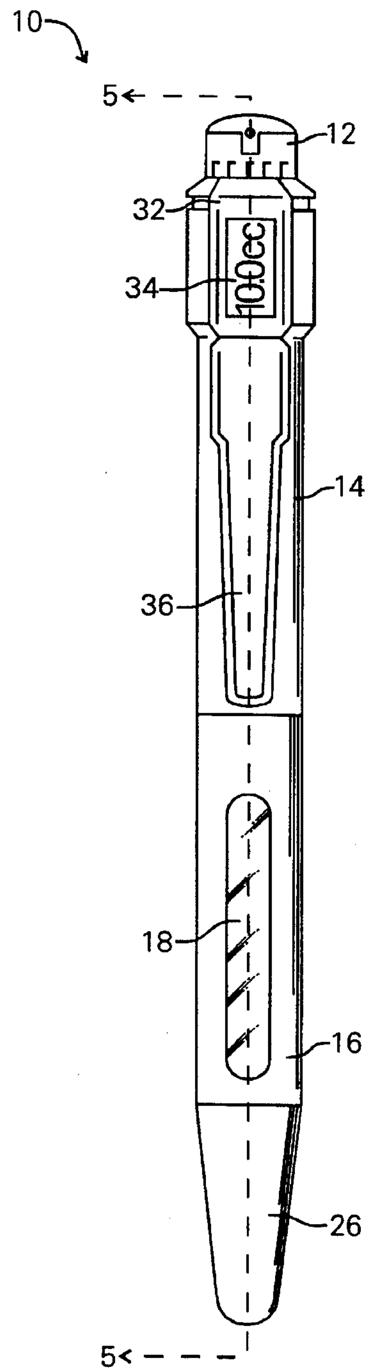

FIG. 2

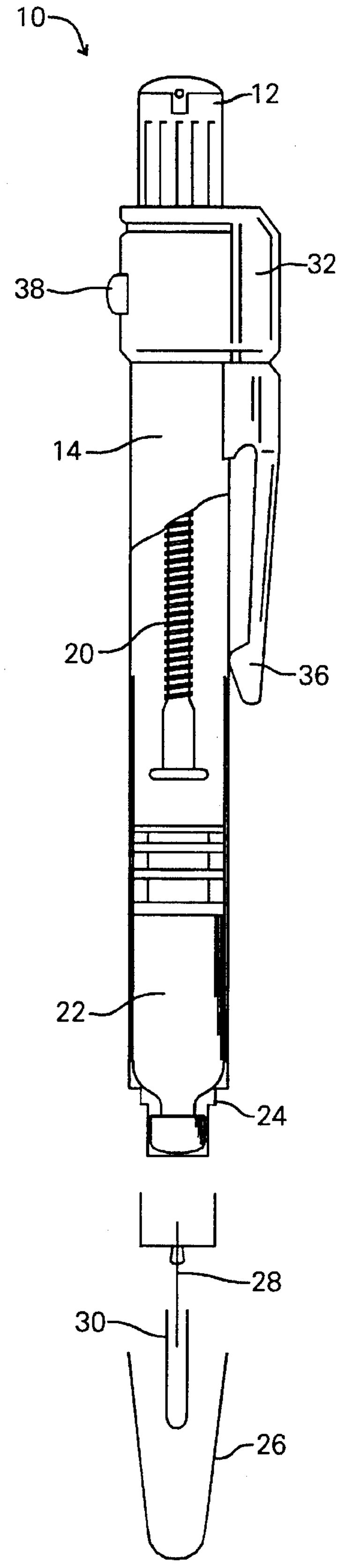

FIG. 3

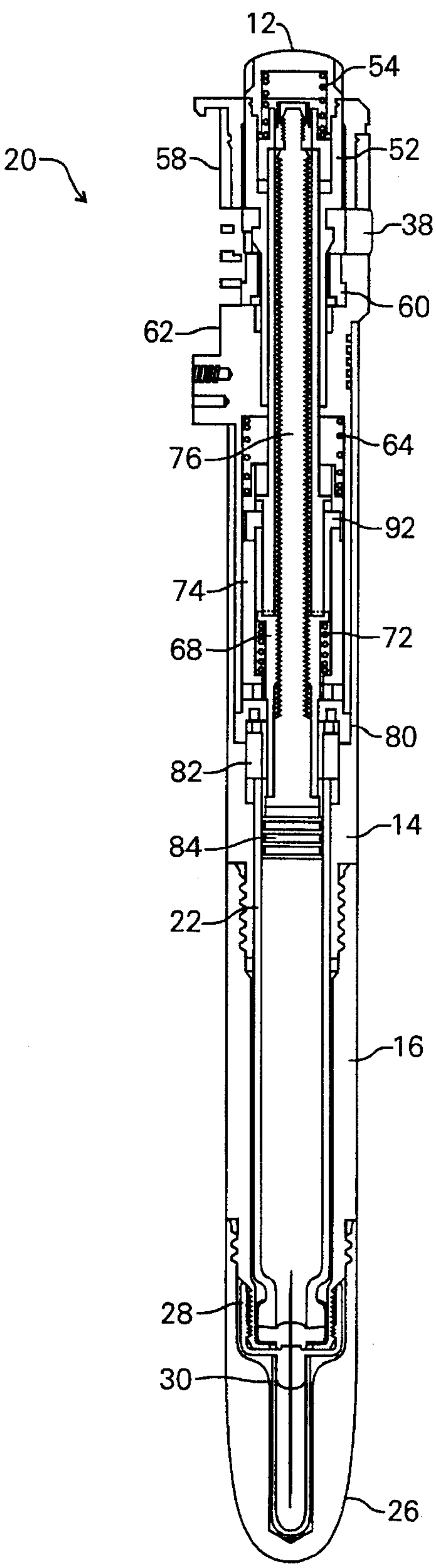
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FIG. 5

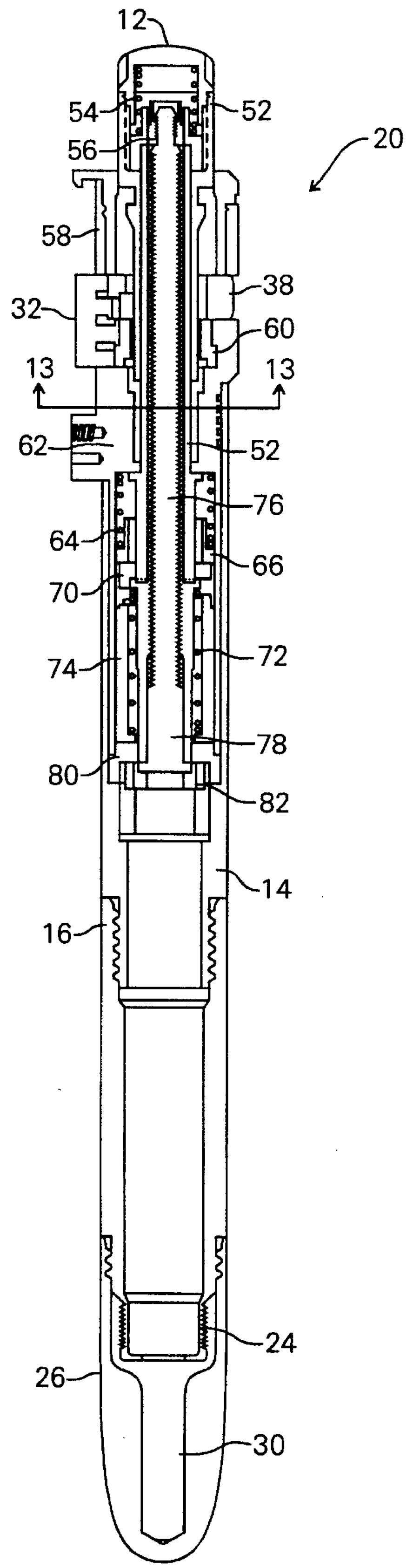
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FIG. 6

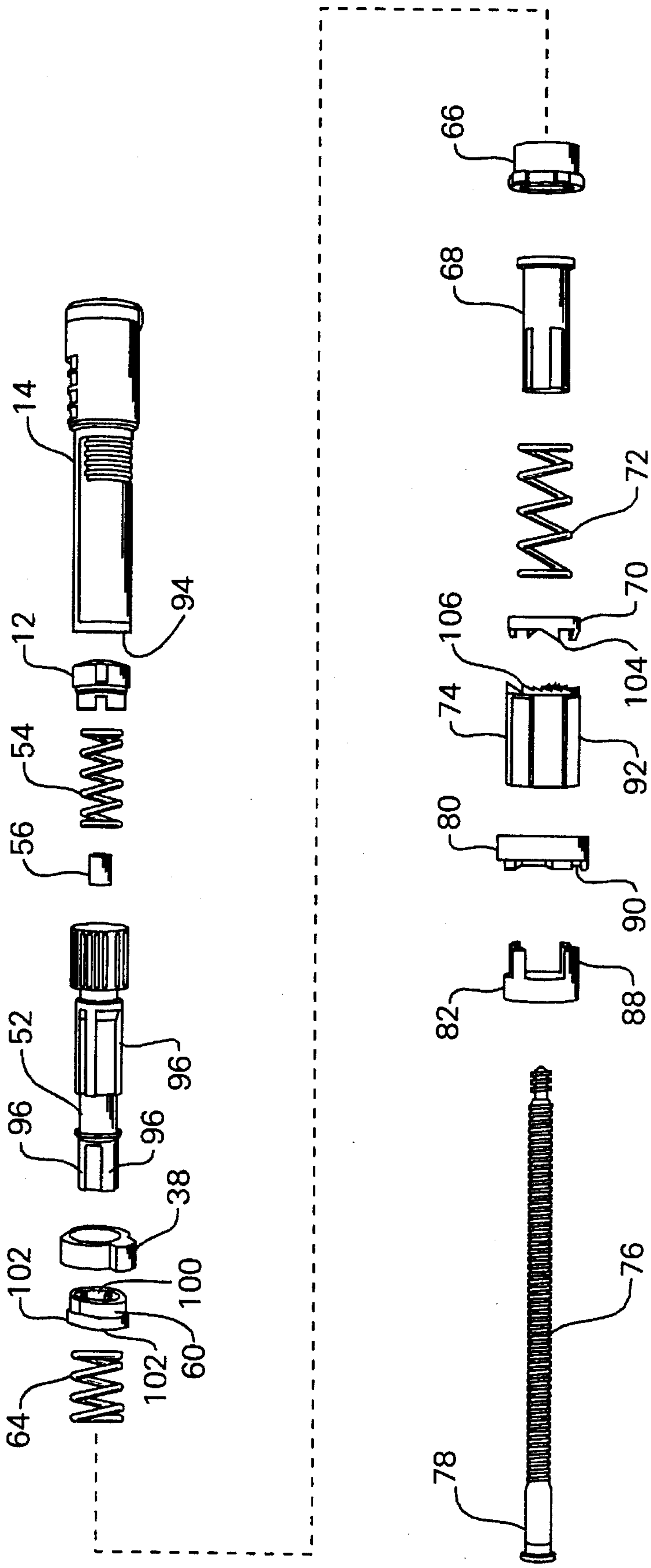
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FIG. 7

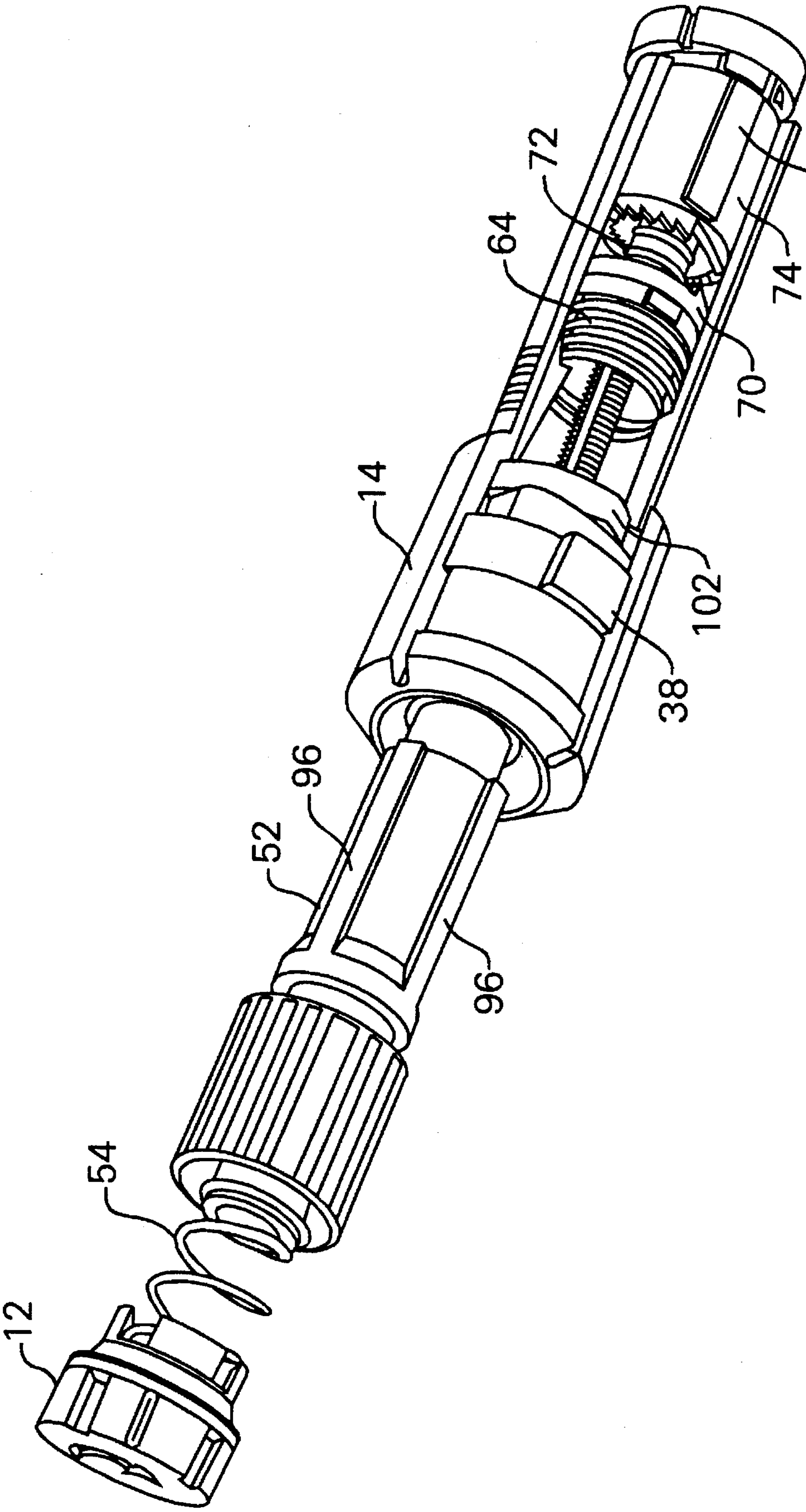


FIG. 8

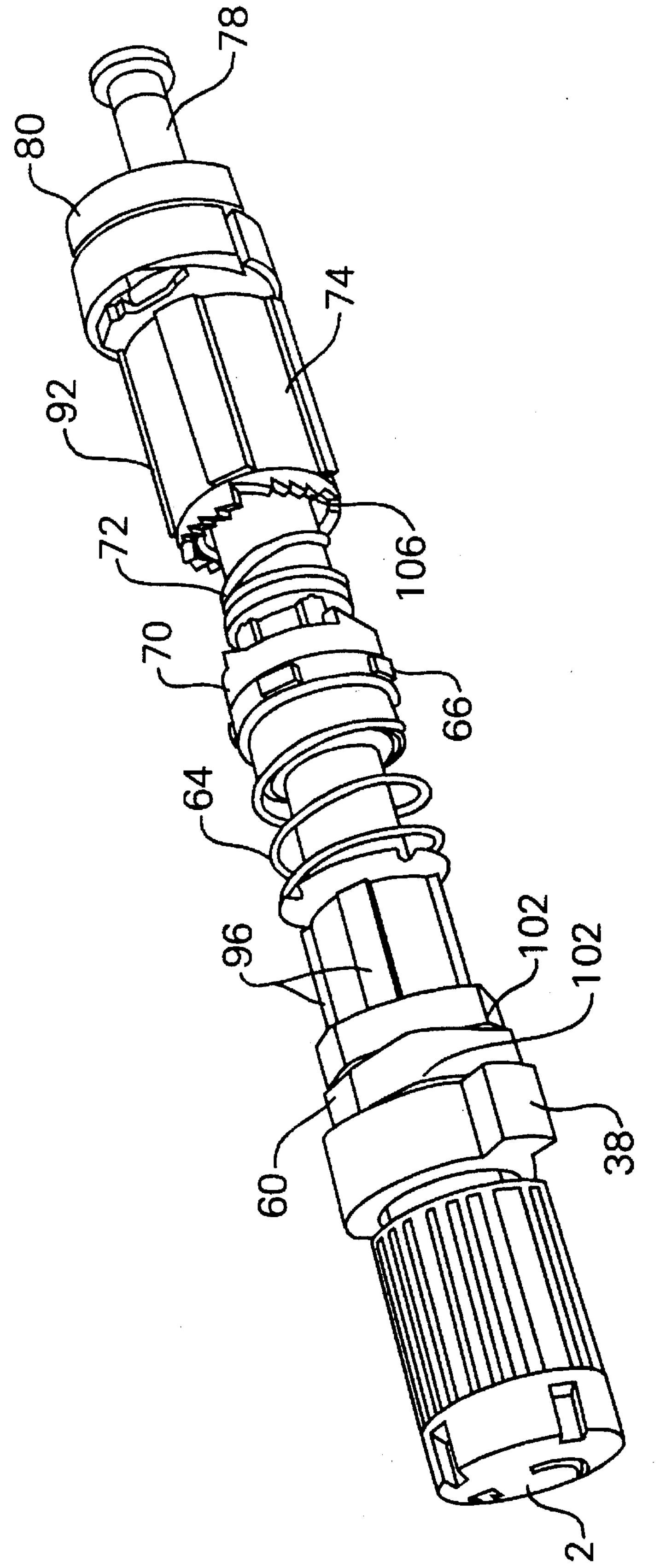


FIG. 9

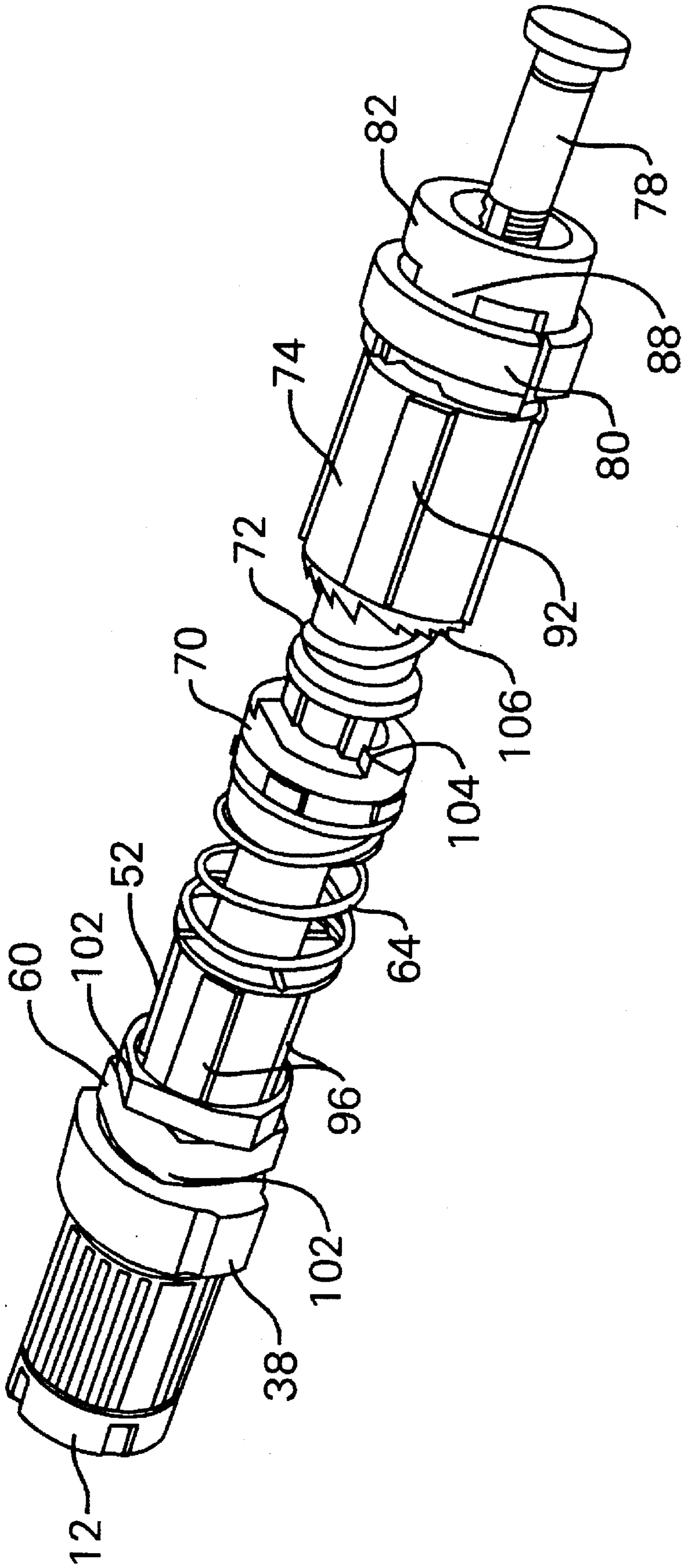


FIG. 10

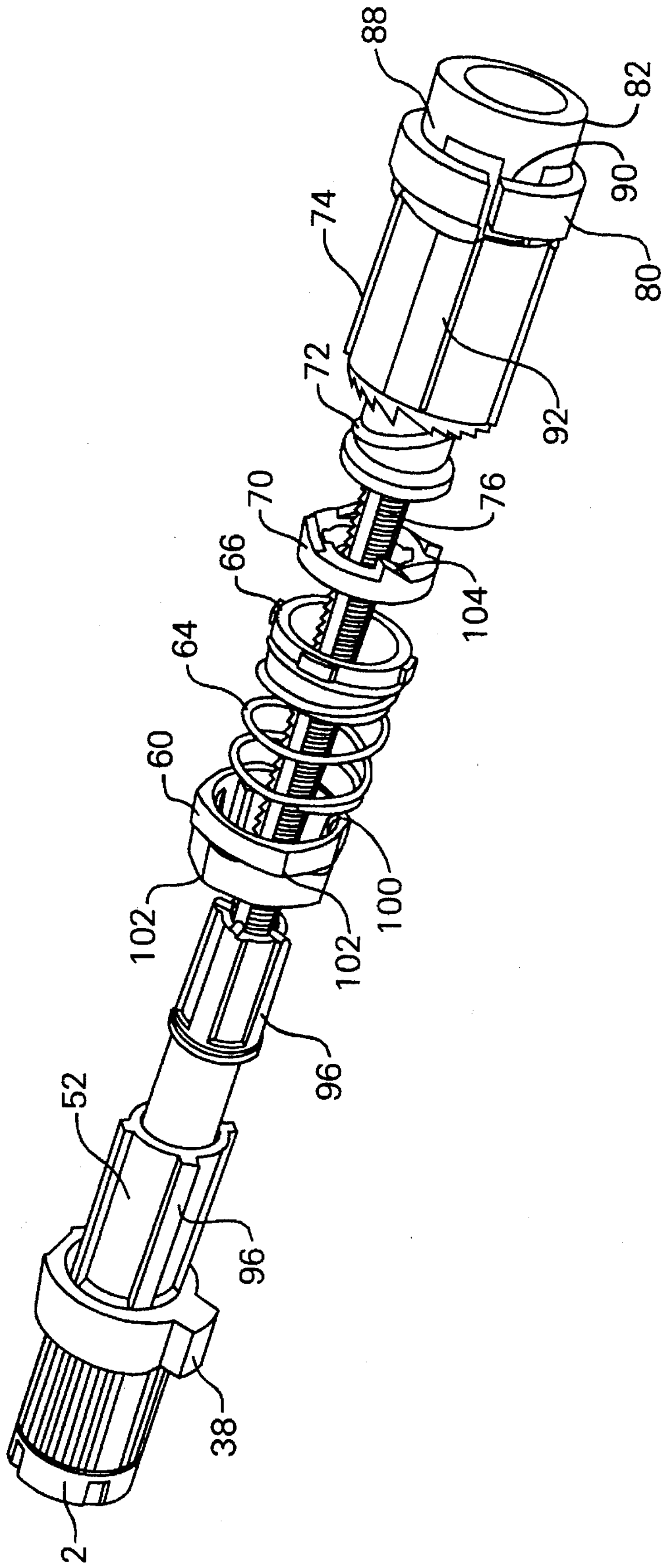
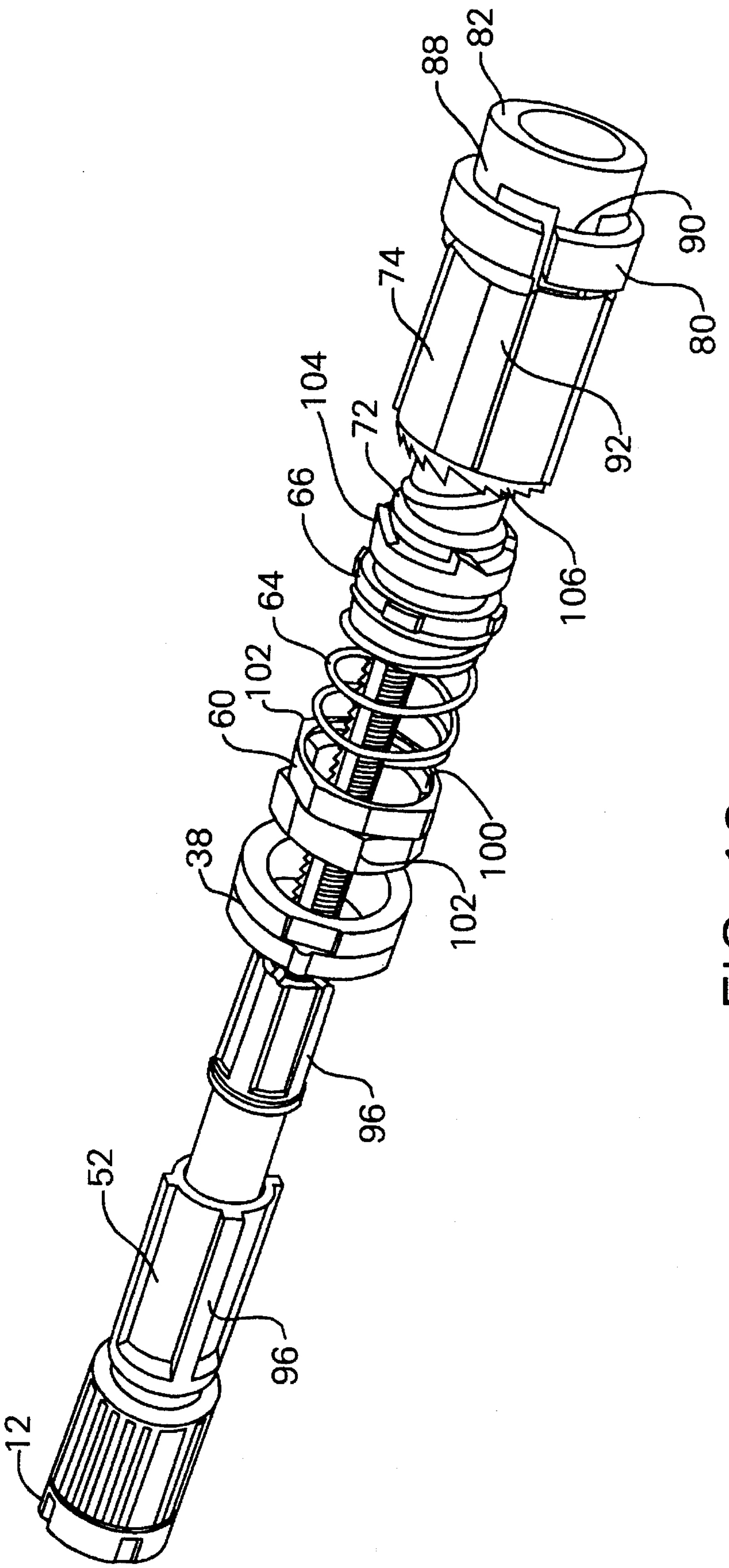


FIG. 11



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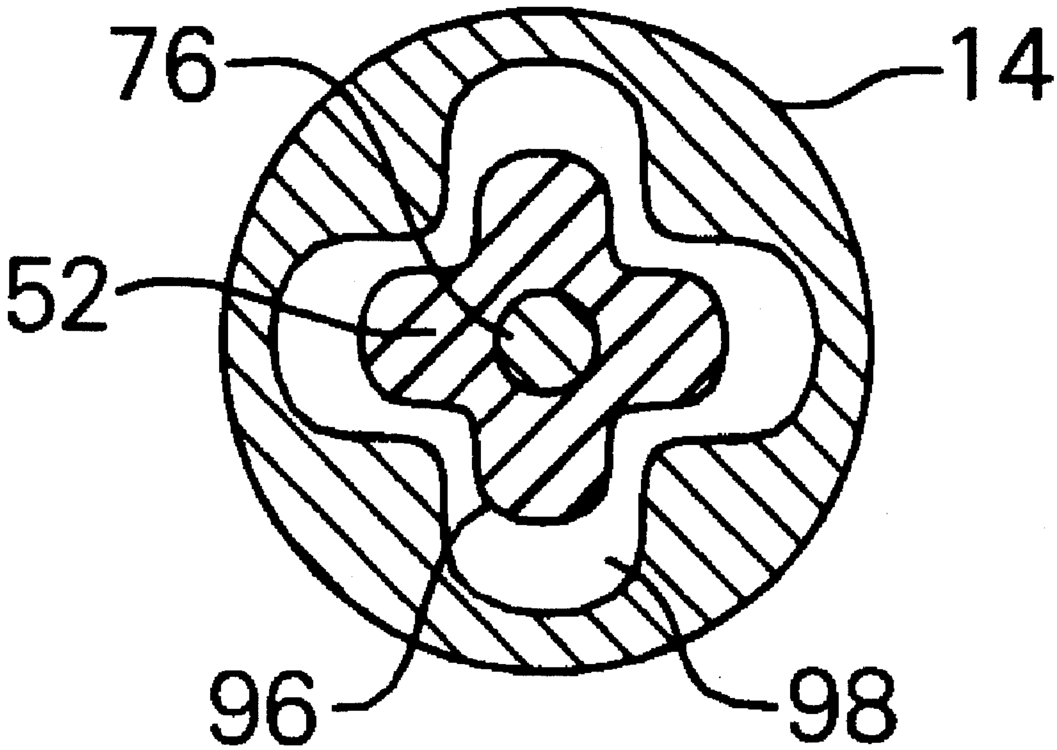

FIG. 13

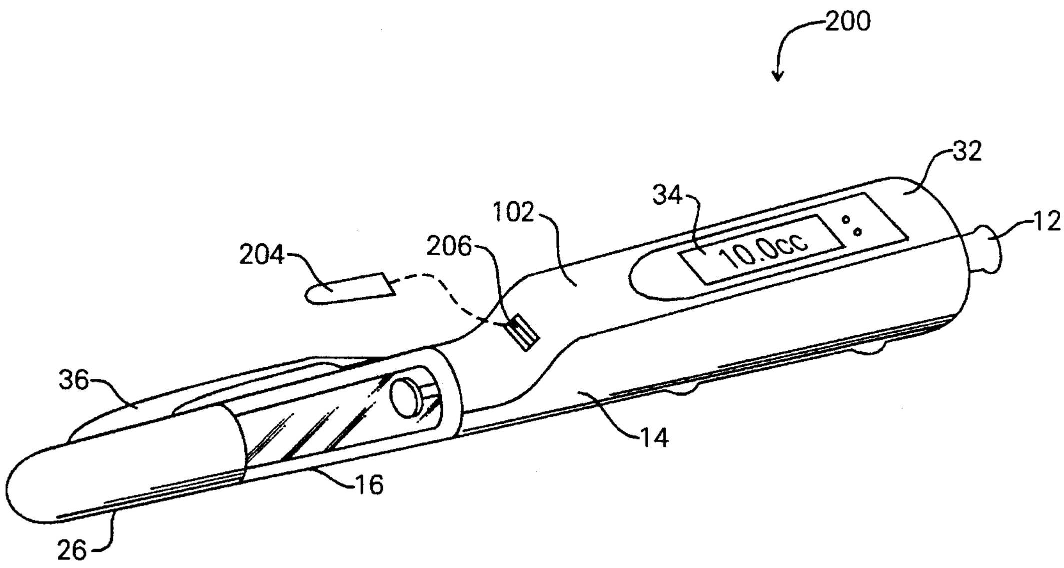
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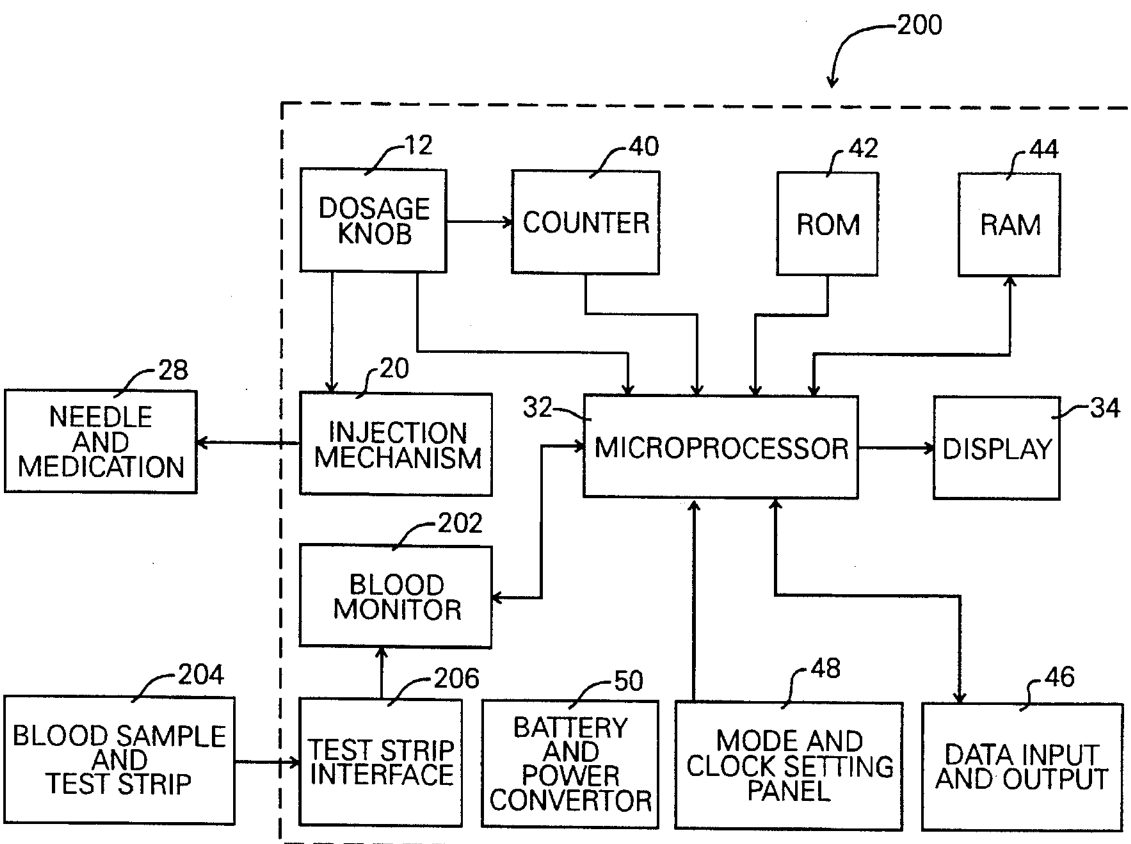
FIG. 14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34
202
BLOOD MONITOR
204
BLOOD SAMPLE AND TEST STRIP
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TEST STRIP INTERFACE
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BATTERY AND POWER CONVERTOR
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MODE AND CLOCK SETTING PANEL
46
DATA INPUT AND OUTPUT

FIG. 15

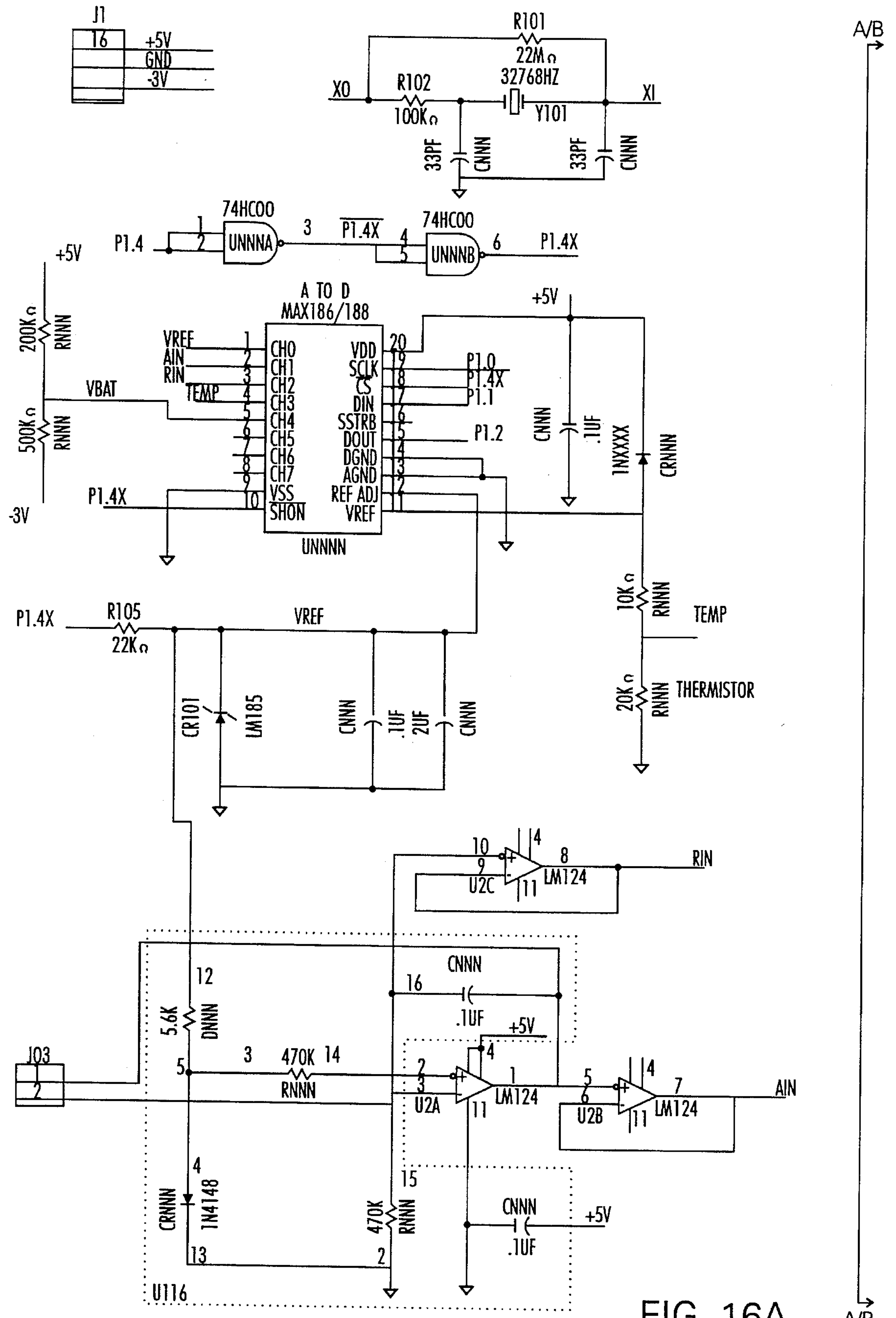

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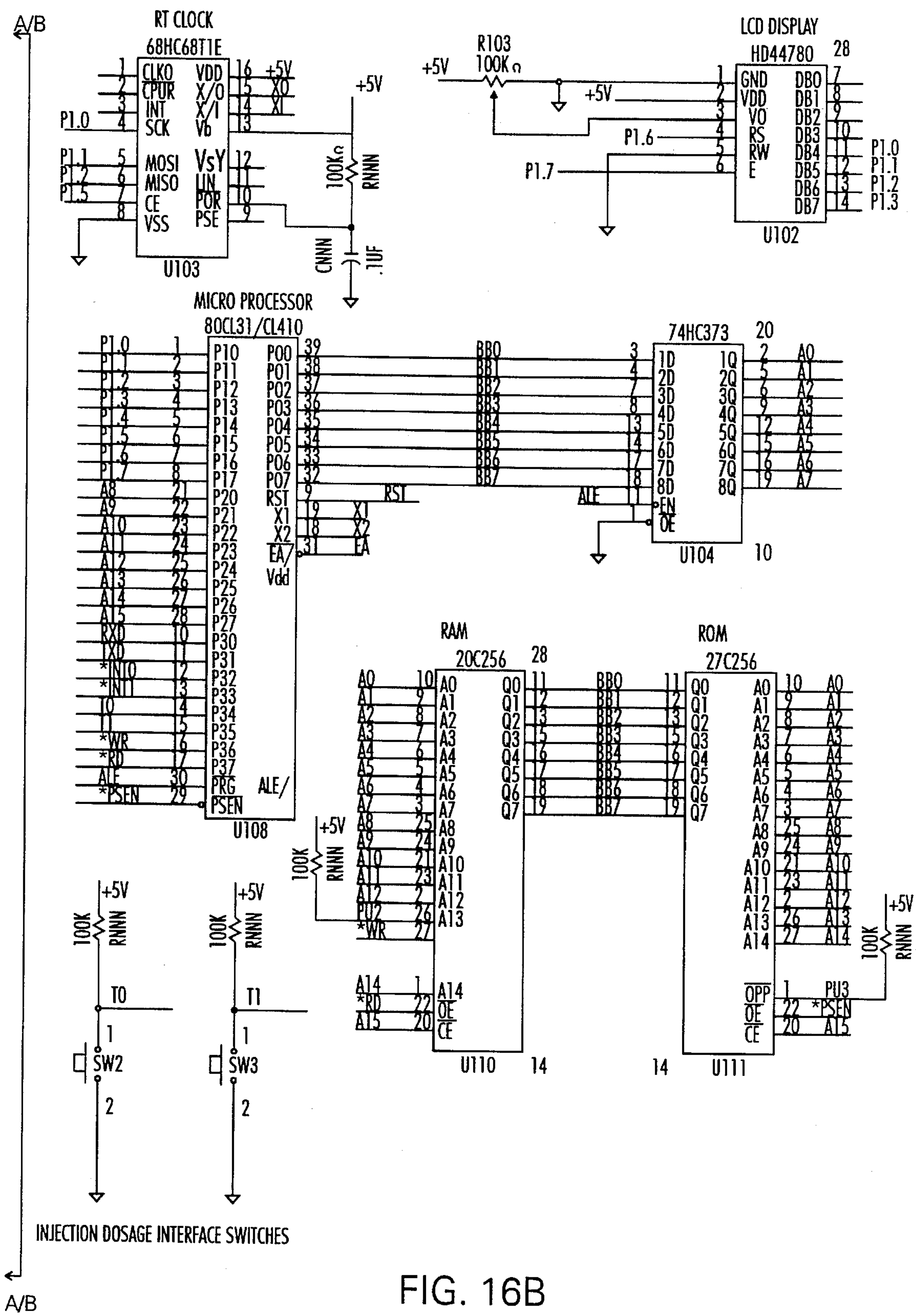
FIG. 16A



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SW2
SW3
INJECTION DOSAGE INTERFACE SWITCHES
A/B

FIG. 16B

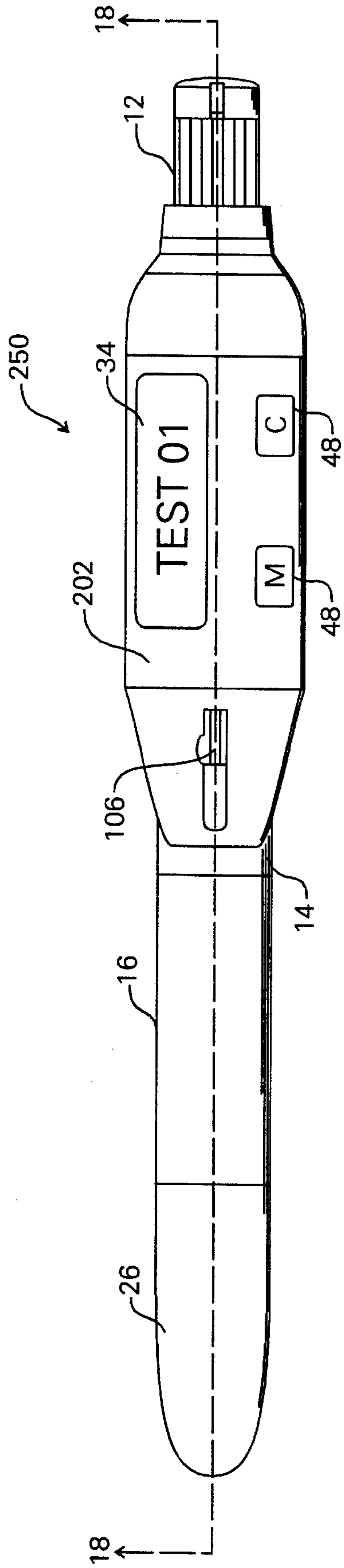

18
12
250
34
TEST 01
C
48
M
48
202
106
14
16
26
18

FIG. 17

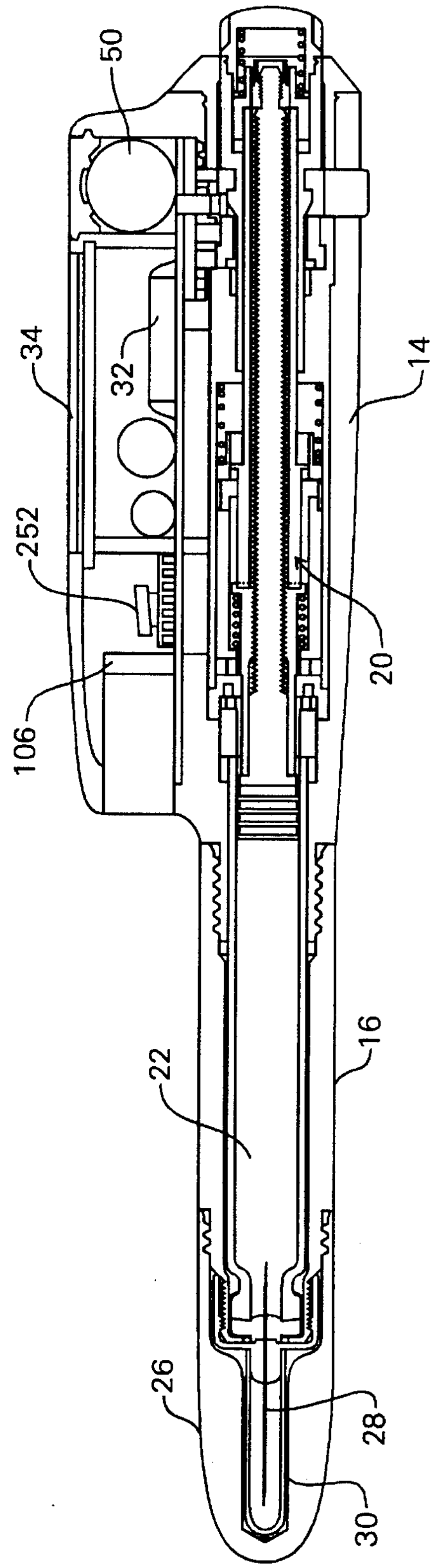

50
34
32
14
252
20
106
22
16
26
28
30

FIG. 18

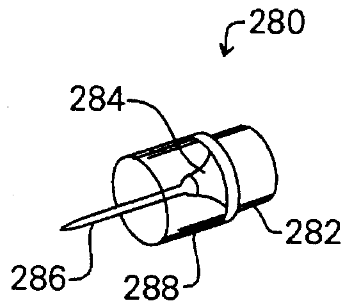


FIG. 19

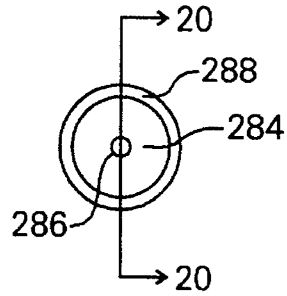


FIG. 20

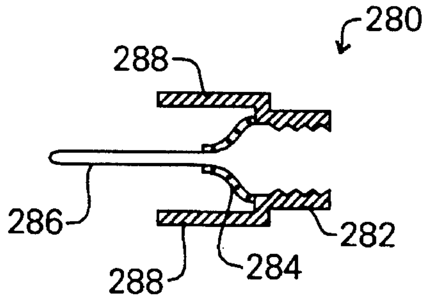
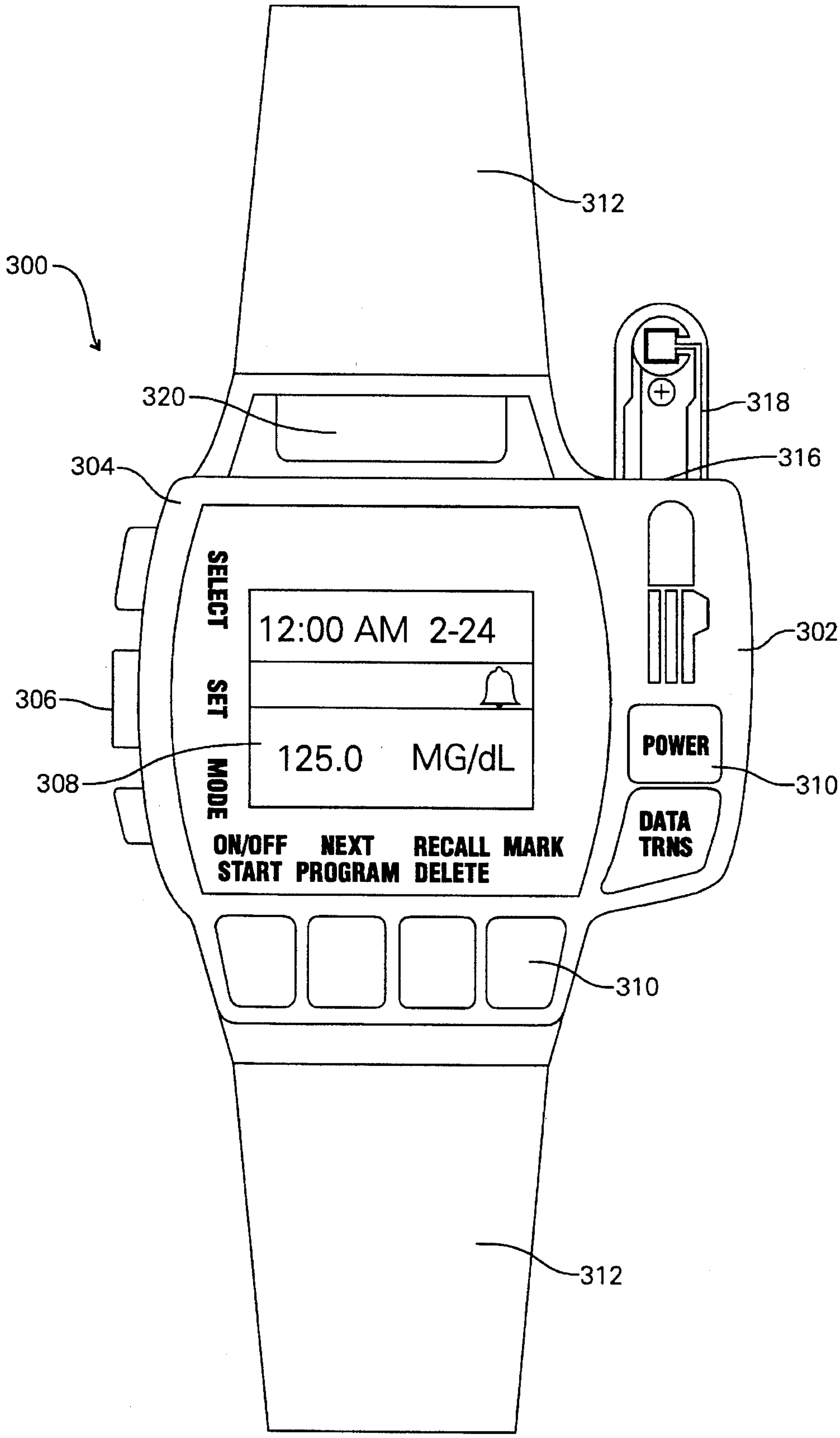


FIG. 21



312
300
320
318
316
304
SELECT
SET
MODE
12:00 AM 2-24
125.0 MG/dL
302
306
308
POWER
DATA
TRNS
310
ON/OFF
START
NEXT
PROGRAM
RECALL
DELETE
MARK
310
312

FIG. 22

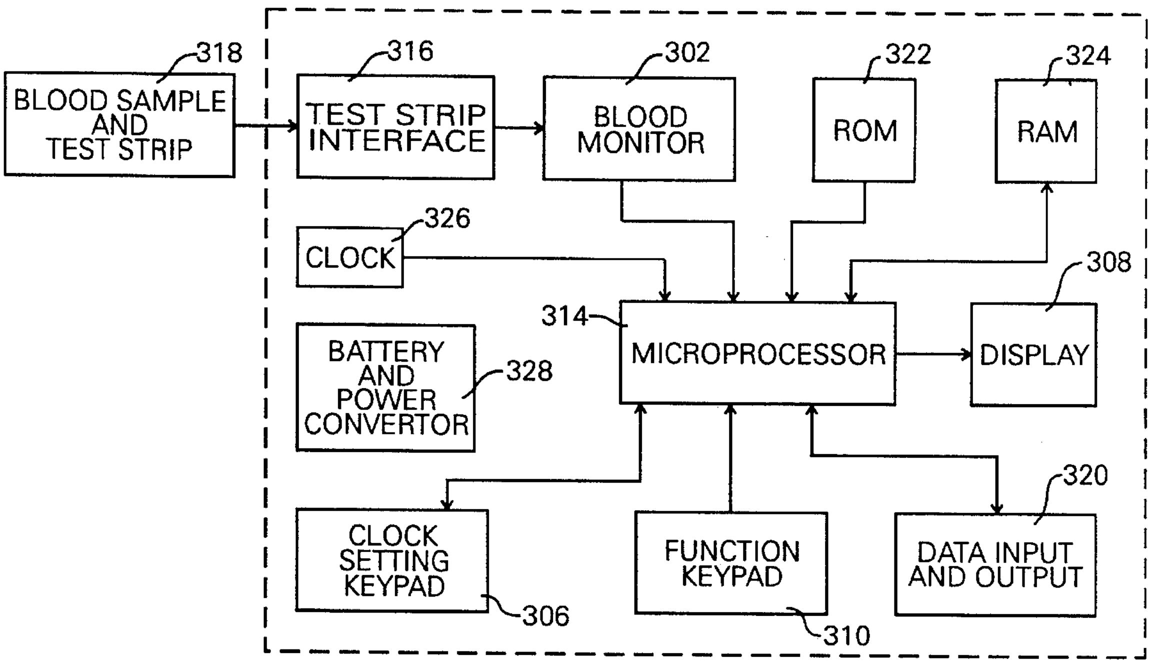

318
BLOOD SAMPLE AND TEST STRIP
316
TEST STRIP INTERFACE
302
BLOOD MONITOR
322
ROM
324
RAM
326
CLOCK
308
314
MICROPROCESSOR
DISPLAY
BATTERY AND POWER CONVERTOR
328
320
CLOCK SETTING KEYPAD
306
FUNCTION KEYPAD
310
DATA INPUT AND OUTPUT

FIG. 23

BLOOD GLUCOSE (mg/dL) INSULIN LOG

Name: Good, Johnny B.	Report Date: 12-31-93
I.D. or Chart #	Report Time: 13:50
Phys/Inst: Cedars S.	Report Span: 12-24 to 12-30-93

	Breakfast		Lunch		Dinner		Snack
	Pre	Post	Pre	Post	Pre	Post	
No. of Readings	7	0	7	0	7	0	7
Std. Deviation	51.0		42.0		61.0		29.0
Average	99.3		113.4		130.4		86.0

FIG. 24(a)

Blood Glucose Chart:

	BLOOD GLUCOSE							
	Breakfast		Lunch		Dinner		Snack	Other
	Pre	Post	Pre	Post	Pre	Post		
12-24-93 Fri	06:30 190		11:24 101		16:41 122		21:25 77	
12-25-93 Sat	06:41 47		11:20 146		16:20 137		21:15 123	
12-26-93 Sun	06:30 59		11:25 113		16:36 156		21:30 111	

FIG. 24 (b)

Insulin Chart:

	INSULIN			
	Breakfast	Lunch	Dinner	Evening
12-24-93 Fri	06:39 R-3 L-7	11:38 R-6 L-6	16:56 R-13 L-11	21:37 R-7 L-12
12-25-93 Sat	06:42 R-2 L-5	11:24 R-3 L-6	16:30 R-10 L-10	21:33 R-6 L-10
12-26-93 Sun	06:36 R-4 L-6	11:30 R-6 L-6	16:40 R-8 L-12	21:40 R-8 L-10

FIG. 24 (c)

Markers Chart:

	MARKERS			
	Symptom	Meal	Exercise	Special
12-24-93 Fri		17:15 inc		
12-25-93 Sat	06:00		18:30	
12-26-93 Sun			18:15 inc	

FIG. 24 (d)

PEN-TYPE INJECTOR WITH A MICROPROCESSOR AND BLOOD CHARACTERISTIC MONITOR

FIELD OF THE INVENTION

This invention relates to pen-type injectors for injecting medications or other injectable substances and, in particular embodiments, a pen-type injector for injecting insulin. In preferred embodiments, the pen-type injector utilizes a microprocessor to record injection information and a monitor to measure blood characteristics. Further embodiments of the invention also relate to blood characteristic monitors that are incorporated into wrist watches.

BACKGROUND OF THE INVENTION

Home treatment methods for the control and management of various diseases are becoming more popular. For instance, high success rates for treatment of diabetes have been achieved when a diabetic patient controls the disease by self-testing blood glucose levels and administering a correct dose of insulin. The doctor works with the patient to determine the best regimen of diet, exercise, and insulin dose to maintain a target blood glucose level.

Between doctor's office visits, the patient is responsible for carrying out the prescribed regimen, which includes frequent blood testing and insulin administration using a syringe, needleless injector, pen-type injector or insulin pump. The patient and doctor select a blood glucose monitor based on desired monitor features, suitability for the patient, perceived accuracy, and ease of use.

Home diabetes therapy requires personal discipline of the user, is time consuming, requires an appropriate location, and the proper instruments and accessories. Therefore, it is highly desirable that the home therapy regimen cause minimal inconvenience and changes in the patient's lifestyle. Many past therapy regimens and devices have failed to provide the convenience and minimum changes to the patient's lifestyle, and thus the compliance with the medical regimens have been less than satisfactory.

Traditionally, for out-patient and in-home patient care, medication has been injected by a syringe, wherein the user has to insert the needle of the syringe into a separate medication vial to withdraw medication. Once the medication is withdrawn from the vial, the user removes any air bubbles and extra medication, and then injects the medication.

Typical syringes suffer from many drawbacks. For instance, they may not be preloaded with medication; thus, requiring the user to carry a separate medication vial. Moreover, people with dexterity disorders often have difficulty lining up the needle portion of the syringe with the rubber septum on the medication vial. This can lead to unintentional needle pricks or excessive time being required to complete an injection, both of which tend to inhibit compliance with a medical regimen. Also, it is often difficult for children or people with failing eyesight to line up the medication with the proper dosage line on the outer casing of the syringe. Furthermore, the user of the syringe is typically responsible for manually recording the date, the time and the dosage in a separate log book so that the doctor can monitor the user's compliance with the prescribed medical regimen.

Another drawback to the traditional syringe is that a syringe is difficult to use in public places. For instance, many schools do not allow students to carry syringes. This prohibition against syringes can cause excessive delays between injections, and thus could complicate a user's medical condition. Moreover, there is also a social stigma attached to using a syringe, since it raises connotations of drug abuse. These drawbacks have been one of the principal reasons why users have abandoned medical regimens requiring the use of syringes in social settings.

As an alternative, pen-type injectors have been developed. The pen-type injectors often use prepackaged insulin. However, these devices have been inherently inaccurate and undependable due to their difficult to read scales and inadequately designed mechanical injection systems. For example, typical pen-injectors require multiple and repeated activations of the injector mechanism to administer a desired dosage. Thus, during administration of an injection, the user must keep track of the number of activations (i.e., depressions) to determine when the required dosage has been delivered.

Another disadvantage to pen-type injectors is that typical disposable needles used on pen-type injectors cause bleeding during the administration of an injection. This results from the disposable needle spreading the opening in the skin at the injection site, thereby allowing the skin to bleed. This bleeding from traditional disposable needles can discourage users from following the medical regimen, and the bleeding also increases the likelihood of spreading infectious diseases.

Often a user who takes certain medications, such as insulin, in a home therapy regimen must also monitor the level of glucose present in the blood at periodic intervals. The test results are used to determine when another injection should be taken or to determine how the user is responding to prior injections. Typically, the blood monitor is a separate device that the user must carry along with the insulin injector or syringe. To use the blood monitor the user must lance a portion of the body (i.e., typically a finger) and take a sample that is analyzed by the monitor. The user then manually records the results, the time and the date in a separate log book.

SUMMARY OF THE DISCLOSURE

According to embodiments of the present invention, a medical injection device, such as a pen-type injector or the like, has a processor coupled to the injector that records the date, the time, and the amount of each injection. The processor may also be coupled to a display to indicate the amount of medication to be injected.

In particular embodiments, a medical injection device includes an injection mechanism that has an actuator for setting the dosage and administering an injection of a medication contained within the injection device. The injection device also has a processor coupled to the actuator of the injection mechanism to determine a value equal to the dosage set by the actuator of the injection mechanism, and a memory device coupled to the processor to store the value determined by the processor. In further embodiments, the injection device also has a receptacle capable of holding the medication and the injection mechanism further includes a drive mechanism coupled between the actuator and the receptacle to inject the set dosage of the medication. In other embodiments, the injection device also includes a display device to display the value equal to the dosage determined by the processor and a clock circuit for determining the time. In preferred embodiments, the injection device includes a data port for transferring information to and from the processor and memory device to an external device.

In particular embodiments of the present invention, a medical device includes a pen-type injector that is also coupled with a blood characteristic monitor to analyze characteristics of the blood. This provides a single, all-in-one device that performs a variety of functions, and requires only minimal space.

In particular embodiments, a medical device includes a medication injector for injecting a dosage of a medication, a blood characteristic monitor for analyzing a blood sample, and a processor coupled to the medication injector and the blood characteristic monitor. The processor determines a value equal to the dosage of the medication to be injected by the medication injector. The processor also determines blood characteristics from a blood sample analyzed by the blood characteristic monitor.

In further embodiments, the medical device also includes a memory device coupled to the processor to store the value equal to the dosage and the blood characteristics determined by the processor. In preferred embodiments, the medical device includes a data port for transferring information to and from the processor and memory device to an external device and a clock circuit for tracking the time.

According to another embodiment of the invention, a pen-type injector utilizes a disposable needle that substantially eliminates or reduces bleeding from an opening in the skin at the injection site. Also in other embodiments, the pen-type injector uses a direct drive mechanism for injecting the medication with a single depression of an actuator knob. Moreover, the actuator knob is rotatable to adjust the amount of medication that is injected.

In particular embodiments, a disposable needle for a pen-type injector has a base adapted to be coupled to a pen-type injector, an injection needle having a injection end and a connecting end, and a hollow cylindrical cover having an open end and an opposite connecting end. Both the connecting end of the injection needle and the opposite connecting end of the hollow cylindrical cover are coupled to the base such that the injection needle is disposed in the center of the open end of the hollow cylindrical cover with the connecting end of the injection needle inside the hollow cylindrical cover below the open end of the hollow cylindrical cover. Moreover, the injection end of the injection needle extends beyond the open end of the hollow cylindrical cover.

According to a further embodiment of the present invention, a watch monitor includes a blood characteristic monitor and a clock that performs as a wrist watch. The watch monitor utilizes a high quality blood analysis device that can record detailed information on blood analysis results and injections. Moreover, the device can be worn easy and unobtrusively on a wrist so that typical time and alarm functions are combined with the blood characteristic monitor to coordinate the blood testing regimen and reduce the number of items a user must carry. Thus, a user has improved detailed record keeping, regimen alarms and reminders, blood characteristic analysis capabilities, and time keeping functions in a single, all-in-one device.

In particular embodiments of the present invention, a portable blood monitor includes a housing of suitable size and configuration to be worn on a wrist, a clock contained in the housing for measuring time, and a blood characteristic monitor contained in the housing for analyzing a blood sample. The portable blood monitor also includes a processor coupled to the blood characteristic monitor and the clock. The processor determines blood characteristics based on the analyzed blood sample from the blood characteristic monitor, and the processor uses the measure of the time from the clock to identify when the blood characteristics were determined. In further embodiments, the portable blood monitor also includes a memory storage device coupled to the processor for storing the measure of time from the clock and the blood characteristics determined by the processor, and a display device to display the measure of the time from the clock and the blood level characteristics determined by the processor. In preferred embodiments, the portable blood monitor includes a data port for transferring information to and from the processor and memory device to an external device and the data port may utilize infrared communication technology to transfer the information.

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, various features of embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description of embodiments of the invention will be made with reference to the accompanying drawings, wherein like numerals designate corresponding parts in the several figures.

FIG. **1** is a perspective view of a pen-type injector in accordance with an embodiment of the present invention.

FIG. **2** is a front perspective view of the embodiment of the pen-type injector shown in FIG. **1**.

FIG. **3** is a partial cross-sectional and exploded side view of the pen-type injector shown in FIG. **2**.

FIG. **4** is a simplified flow block diagram for the pen-type injector as shown in FIG. **1**.

FIG. **5** is a cross-sectional view of the pen-type injector embodiment as shown along the line **5—5** in FIG. **2**.

FIG. **6** is another cross-sectional view of the pen-type injector shown in FIG. **5**, with the actuator in the released position.

FIGS. **7–12** show various perspective views of a drive mechanism in accordance with an embodiment of the present invention.

FIG. **13** is a cross-sectional view of the pen-type injector as shown along the line **13—13** in FIG. **6**.

FIG. **14** is a perspective view of a pen-type injector that includes a blood characteristic monitor in accordance with an embodiment of the present invention.

FIG. **15** is a simplified flow block diagram for the pen-type injector with a blood characteristic monitor as shown in FIG. **14**.

FIGS. **16A** and **16B** are a circuit schematic for the pen-type injector with a blood characteristic monitor shown in FIGS. **14** and **15**.

FIG. **17** shows a top view of another pen-type injector with a blood characteristic monitor in accordance with an embodiment of the present invention.

FIG. **18** is a cross-sectional view of the pen-type injector with a blood characteristic monitor as shown along the line **18—18** in FIG. **17**.

FIG. **19** is a perspective view of a disposable needle in accordance with an embodiment of the present invention.

FIG. **20** is an end view of the disposable needle as shown in FIG. **19**.

FIG. **21** is a cross-sectional view of the disposable needle as shown along the line **21—21** in FIG. **20**.

FIG. **22** is a front plan view of a blood characteristic monitor in accordance with an embodiment of the present invention.

FIG. **23** is a simplified flow block diagram in accordance with the embodiment shown in FIG. **22**.

FIGS. **24**(*a*)–**24**(*d*) are diagrams of typical reports obtained from the embodiment shown in FIGS. **22** and **23**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the invention is embodied in a pen-type injector utilizing a microprocessor. In particular embodiments of the present invention, the pen-type injector further includes a blood characteristic monitor to measure characteristics of a blood sample. In further embodiments, the pen-type injector uses a direct drive injection mechanism, and may include a disposable needle which substantially eliminates or reduces bleeding caused from administration of an injection. In other embodiments, a blood characteristic monitor is contained within a wrist watch sized device that combines blood characteristic monitoring, time keeping and information recording in a single, all-in-one device that is worn on a user's wrist.

In preferred embodiments of the present invention, the pen-type injector is used to inject insulin, and the blood characteristic monitor is used to determine the amount of glucose present in a blood sample. However, it will be recognized that further embodiments of the invention may be used with other types of medication or other injectable substances, such as vitamins, growth hormones or the like. Moreover, embodiments of the present invention may be used with other types of injectors that are not pen shaped, such as jet injectors and the like. Furthermore, in other embodiments, the blood characteristic monitor may be used to monitor other characteristics, such as hormone levels, cholesterol levels or the like.

Embodiments of the present invention combine pen-type injectors with a microprocessor to accurately set and determine the dosage of a medication that is injected into the user. Moreover, the microprocessor serves to record important information concerning the injection, such as the date, the time and the amount of medication injected. This information is displayed on an LCD display, or the like, for easy review by the user or doctor. This allows the user to carry one self-contained injection device that does not require carrying a separate medication vial and syringes, since the vial is contained within the injector. Moreover, the user does not have to carry a separate log book to record relevant and required information concerning the injection, since this information is automatically recorded by the microprocessor for later recall.

A preferred embodiment of the pen-type injector has a direct drive injection mechanism for accurate dosing and ease of use. The drive utilizes a rotatable dosage knob provided at one end of the pen-type injector. The dosage knob allows the user to accurately adjust the amount of medication or insulin that will be injected by the pen-type injector, since rotating the dosage knob limits the distance that the dosage knob can be depressed. Accuracies of 0.001 to 0.01 ccs (0.1 to 1.0 units) can be readily achieved. To inject a dose of medication, the user inserts the needle under the skin and depresses the dosage once knob once as far as it will depress.

In preferred embodiments, the pen-type injector is also combined with a blood characteristic monitor that determines the level of medication in a blood sample. The blood characteristic monitor uses the microprocessor in the pen-type injector (although a separate microprocessor could be used) to process the blood sample results and to store relevant information about the results. Thus, a single, all-in-one device provides medication injection, blood characteristic monitoring, and record keeping. Therefore, a user is only required to carry a single device, and is not required to carry a large number and variety of items to comply with their medical regimen. For example, a separate medication vial, a separate medication injector, a separate blood characteristic monitor and a separate log book are not needed.

In other embodiments, the pen-type injector utilizes a disposable needle that minimizes or substantially eliminates the bleeding that may occur from administering an injection. The disposable needle includes a protective, hollow cylindrical cover that prevents the user from pushing the needle too deeply into the skin. Moreover, the hollow cylindrical cover tends to press the skin together during the administration of an injection to restrict and substantially eliminate bleeding during the injection.

In another preferred embodiment of the present invention, a portable blood monitor combines a blood characteristic monitor with a wrist watch. The blood characteristic monitor is coupled to a microprocessor to analyze blood samples and record relevant data for later recall. The wrist watch performs time keeping functions and provides alarms to notify the user when to monitor blood characteristics and when to administer injections. In particular embodiments, the portable blood monitor has a plurality of keys that allow the user to input additional information concerning injections and special events. In other embodiments, the portable blood monitor includes a data input and output port to provide the capability of programming the portable blood monitor through an external computer, such as a PC, lap top or the like, and to provide for the capability to download the stored information to an external computer for detailed review and analysis by the user or doctor.

FIGS. **1–3** show a pen-type injector **10** with a microprocessor **32** in accordance with an embodiment of the present invention. The pen-type injector **10** includes a rotatable actuator dosage knob **12**, an injection housing **14**, and a medication cartridge housing **16** having a view window **18**. The actuator knob **12** is coupled to one end of the injection housing **14**, and is also operatively coupled to an injection mechanism **20** (see FIG. **3**) that is contained within the injection housing **14**. The medication cartridge housing **16** is sized to hold a medication cartridge **22** (see FIG. **3**) and is coupled to the other end of the injection housing **14** so that the injection mechanism **20** is operatively coupled to the medication cartridge **22**. In preferred embodiments, the medication cartridge housing **16** is coupled to the injection mechanism housing **14** by threads, and the medication cartridge **22** is connected to the medication cartridge housing **16** by threads, a friction fit or the like. In particular embodiments, the medication cartridge **22** contains 1.5 ccs (150 units); however, medication cartridges containing more or less medication may be used. In preferred embodiments, the medication cartridge **22** is a Novolin® cartridge by Novo Nordisk Pharm, Inc. or an insulin cartridge by Eli Lilly, Inc.

The view window **18** of the medication cartridge housing **16** allows the user to view the interior contents of the medication cartridge **22**. Thus, a user can visually determine when a medication cartridge **22** needs to be replaced with a refill medication cartridge **22**, or the user can visually determine the type of medication that is currently contained in the medication cartridge housing **16**.

Coupled to the other end of the medication cartridge housing **16** is a needle base **24** for holding a protective needle cover **26** and a disposable needle **28**. The needle cover **26** and the disposable needle **28** are detachably coupled to the needle base **24** by threads, friction or the like. The protective needle cover **26** prevents needle pricks until an injection is to be administered. The use of a disposable needle **28** reduces the chances of spreading infections and allows the pen-type injector to be used multiple times. In preferred embodiments, the disposable needle **28** also includes a protective needle sheath **30** to further reduce the likelihood of unintended needle pricks. In particular embodiments, the pen-type injector uses a 27 gauge disposable needle **28**; however, other gauges may be used.

Also attached to the injection mechanism housing **14** is a microprocessor **32**, a display **34** and a clip **36**. The microprocessor **32** accurately determines the dosage of the medication to be injected based upon the rotations of the actuator knob **12** by the user. The microprocessor **32** provides the dosage information to the display **34** to inform the user of the amount of medication that will be injected. In particular embodiments, the display **34** may include a set of user actuatable buttons to set various parameters in the microprocessor, such as the time, the date or the like. The clip **36** attached to the injection mechanism housing **14** provides the capability for the pen-type injector **10** to be carried around like a traditional ball point pen. For example, the pen-type injector **10** can be carried unobtrusively in a shirt pocket or on a clip board.

As shown in FIG. **3**, the injection mechanism housing **14** also includes a start button **38**. The start button **38** releases the actuator knob **12** from the position shown in FIGS. **1–2** to the released position shown in FIG. **3**. The start button **38** locks the actuator knob **12** in the depressed position to prevent accidental discharges of the medication until an injection is to be administered. The start button **38** also activates the microprocessor **32** only when the microprocessor **32** is needed, and this reduces the overall power consumption characteristics of the device.

In preferred embodiments, the actuator knob **12**, the injection housing **14**, the medication cartridge housing **16**, the needle base **24**, the protective needle cover **26**, and the start button **38** are formed from a plastic material. However, in alternative embodiments, some or all of these parts may be formed from metals, ceramics or other suitable materials. In preferred embodiments, the view window **18** is formed from plastic; however, glass may be used in alternative embodiments. In preferred embodiments, the display **34** is an LCD display; however, in other embodiments, the display may use fluorescent elements, LEDs or the like.

FIG. **4** illustrates a simplified flow block diagram of the pen-type injector **10** shown in FIGS. **1–3**. The actuator dosage knob **12** is rotated to adjust the injection mechanism **20** and set the dosage of the medication to be injected by the disposable needle **28**. In preferred embodiments, the actuator knob **12** can be rotated in two directions to both increase or decrease the dosage level. The actuator knob **12** is coupled to a counter **40** that keeps track of the incremental rotations of the actuator knob **12** and injection mechanism **20**. In particular embodiments, the counter **40** is an electronic counter, and in preferred embodiments the electronic counter is bi-directional and can increment and decrement the dosage level. The counter **40** is coupled to the microprocessor **32** to provide the current count in the counter **40** to the microprocessor **32**. The current count from the counter **40** is converted into a value equal to the dosage of the medication that will be administered by an injection. The actuator knob **12** is also coupled directly to the microprocessor **32** to activate the microprocessor **32**. Thus, when the start button **38** releases the actuator knob **12**, the microprocessor **32** is prepared to store relevant information concerning the injection. For instance, the microprocessor **32** will store, the time, the date and the amount of medication injected by the user.

The microprocessor **32** is coupled to a ROM **42** and a RAM **44**. In preferred embodiments, the ROM **42** is an EPROM and the RAM **44** is a static RAM; however, other comparable memory storage components may be used. The ROM **42** stores the programs used by the microprocessor **32** to determine various parameters, such as the amount of medication to be injected based upon the count from the counter, the date and the time, and how to report information to the user. The RAM **44** is used by the microprocessor **32** to store information about the injection for later recall by the user or the doctor. For example, a user or doctor can transcribe the stored information at a later time to determine compliance with the medical regimen. This is accomplished by downloading the information to the display **34** and then transcribing all of the stored records at one time as they appear on the display **34**.

In preferred embodiments, the microprocessor **32** is coupled to a data input and output (I/O) port **46**, and the user can download the stored information to an external computer (not shown) through the data I/O port **46**. The data I/O port **46** is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor.

Also coupled to the microprocessor **32** is a mode and clock setting panel **48** that provides the user with the capability to store additional information, set the date and the time, or set alarms to indicate when to take the next injection. The panel **48** is used in conjunction with the display **34** to access the various modes and alarms utilizing methods typically employed to set the time on an LCD watch or the like.

The pen-type injector **10** also includes a self contained battery and power convertor **50**. The battery is a small watch type battery, or in preferred embodiments, the battery is a lithium battery capable of providing power for up to 5 years.

Operation of the embodiment shown in FIGS. **1–4** is relatively simple. The user prepares the pen-type injector **10** by depressing the start button **38** to activate the microprocessor **32**. If a new medication cartridge **22** is required, the user unscrews the medication cartridge housing **16** from the injection mechanism housing **14**, and couples a pre-filled medication cartridge **22** to the injection mechanism **20** and the injection mechanism housing **14**. Once the medication cartridge **22** is attached, the user rescrews the medication cartridge housing **16** onto the injection mechanism housing **14**. Next, the user removes the protective needle cover **26**, and attaches a disposable needle **28** to the needle base **24**. The user then holds the pen-type injector **10** with the disposable needle **28** pointing upward and rotates the actuator knob **12** to set a small amount of medication (typically 2–4 units). The user then depresses the actuator knob **12** to eliminate the small amount of medication and remove the air from the disposable needle **28**. Depression of the actuator knob **12** also turns off the microprocessor **32** and prevents accidental discharge of the medication until an injection is to be administered. Finally, the user reattaches the protective needle cover **26** to prevent inadvertent needle pricks or damage to the disposable needle **28**.

To give an injection with the pen-type injector **10**, the user removes the protective needle cover **26** and, if present, the

protective needle sheath **30**. The actuator knob **12** is released and the microprocessor **32** is activated by depressing the start button **38**. In preferred embodiments,, when activated, the microprocessor **32** displays the time and the amount of the last injection on the display **34** in an alternating sequence for 5 seconds (although longer or shorter periods may be used) to remind the user of the last injection event. This substantially reduces the chance of "double dosing" (i.e., taking too much medication). After the reminder display, the pen-type injector **10** automatically zeros itself so that the user can dial in and set the dosage by rotating the actuator knob **12** in one direction (typically clockwise) until the desired amount of the medication to be injected is displayed on the display **34**. In particular embodiments, the display **34** changes in real time, and in preferred embodiments, an audible click or beep is heard as the user rotates the actuator knob **12**. Also in preferred embodiments, each click represents an incremental change in the dosage selected (i.e., 0.1, 0.25, 0.5 or 1.0 units). In bi-directional models, the user can increase or decrease the amount of medication to be injected. However, the microprocessor **32** will not allow the user to set a dosage below zero or to select a dosage larger than the amount of medication remaining in the medication cartridge **22**.

After the dosage is selected, the user chooses an injection site, pushes the disposable needle **28** under the skin and depresses the actuator knob **12** down as far as it will go. The actuator knob **12** automatically locks in the depressed position when the actuator is depressed completely and the injection is completed. When the actuator knob **12** is depressed, the microprocessor **32** stores the injection event in the RAM **44** by the date, the time and the amount of injected medication. When the user returns home or after a certain number of injections have been administered, the user can activate the microprocessor **32** with the mode and clock setting panel **48** to review the recorded data as it is displayed on the display **34**. The patient can transcribe this information in a separate log book if desired. When the user visits the doctor, the doctor can download all the stored injection information into an external computer via the data I/O port **46**. The doctor can then review the data to spot trends and determine compliance with the medical regimen. If required, the doctor can update the program instructions in the pen-type injector **10** via the data I/O port **46** to provide reminder alarms at various times.

FIGS. **5** and **6** show detailed cross-sectional views of a preferred embodiment of a direct drive injection mechanism **20** as shown along the line **5—5** in FIG. **2**. FIGS. **7–12** show various perspective views that detail the drive mechanism **20** shown in FIGS. **5** and **6**. FIG. **13** is a cross-sectional view of the drive mechanism **20** along the line **13—13** shown in FIG. **6**. The drive mechanism **20** includes a dosage knob drive shaft **52**, a tension spring **54**, a lock nut **56**, a display seat **58**, an offset camshaft **60**, an electronics mount **62**, a ratchet spring **64**, a ratchet collar **66**, a drive calibrator **68**, a ratchet gear **70**, a synchronizer spring **72**, a stationary synchronizer **74**, a threaded drive shaft **76**, a plunger **78**, an end cap **82**, a medication cartridge tensioner and synchronizer **82**, and a medication cartridge plunger **84** that are coupled as shown in FIGS. **5–12**.

The dosage knob drive shaft **52** of the actuator knob **12** is coupled to the threaded drive shaft **76** by a threaded lock nut **56** to secure the actuator knob **12** to the drive shaft **76**. The start button **38** is also coupled to the actuator knob **12** by the dosage knob drive shaft **52** to maintain the actuator knob **12** in a depressed position when the pen-type injector **10** is not being used, and to release the actuator knob **12** and activate

the microprocessor **32** when the pen-type injector **10** is to be used for an injection. Contained within the actuator knob **12** is a tension spring **54** which is securely attached to the interior of the actuator knob **12**. The purpose of the tension spring **54** is to apply pressure to the drive shaft **76** to maintain the drive shaft in a fixed position after each injection and to facilitate movement of the threaded drive shaft **76** toward the medication cartridge **22** during an injection.

The dosage knob drive shaft **52** has splines **96** which, when the actuator knob **12** is in the depressed position, are locked in corresponding spline slots **98** of the injection mechanism housing **14** to prevent the actuator knob, the dosage knob drive shaft **52** and the threaded drive shaft **76** from being rotated. When the actuator knob **12** is released by the start button **38**, the actuator knob **12** and the dosage drive shaft **52** move in a direction away from the medication cartridge **22**. The splines **96** slide clear of the spline slots **98** so that the actuator knob **12**, the dosage knob drive shaft **52** and the threaded drive shaft **76** can be rotated as a single unit to adjust the dosage of medication that will be injected by the pen-type injector **10**.

The splines **96** of the dosage drive shaft **52** are also coupled to spline slots **100** of the offset camshaft **60** which is coupled to the counter **40** mounted on the electronics mount **62**. The offset camshaft **60** has cam lobes **102** that are in operative contact with the counter **40**. When the actuator knob **12** is rotated, the dosage knob drive shaft **52** rotates the offset camshaft **60** and the cam lobes **102** to increment the counter by one count per each predetermined angle of rotation of the actuator knob **12**, the dosage knob drive shaft **52**, the threaded drive shaft **76** and the offset camshaft **60**. In preferred embodiments, the predetermined angle of rotation is 90° (although larger or smaller angles may be used).

The display seat **58** is adapted to hold the display **34** and the microprocessor **32**. The microprocessor **32** is coupled to the counter **40** that is mounted on the electronics mount **62** to determine the dosage of medication to be injected based upon the value in the counter **40**. The display seat **58** may also be used to hold the clip **36** to allow the pen-type injector **10** to be carried like a pen.

The ratchet spring **64** is permanently attached to the interior of the injection mechanism housing **14**. The ratchet spring **64** applies pressure to the ratchet collar **66** which in turn applies pressure to the ratchet gear **70**. The ratchet gear **70** has teeth **104** that mate correspondingly with teeth **106** on the stationary synchronizer **74**. The synchronizer spring **72** applies a counter pressure on the stationary synchronizer **74** to maintain the ratchet gear **70** and the stationary synchronizer **74** in contact with each other. Thus, when the actuator knob **12** is rotated, a ratchet noise is produced as the ratchet gear **70** is rotated relative to the stationary synchronizer **74**. Removal of the medication cartridge **22** reduces the pressure on synchronizer spring **72** so that the corresponding teeth **104** and **106** of the ratchet gear **70** and the stationary synchronizer **74** are disengaged. When the teeth **104** and **106** are disengaged, the actuator knob **12** can be rotated easily with minimal resistance, and the threaded drive shaft **76** can be withdrawn without resistance from the ratchet gear **70**.

The stationary synchronizer **74** also has splines **92** which are coupled to corresponding spline slots **94** in the injection mechanism housing **14** to prevent the stationary synchronizer **74** from rotating. However, the splines **92** are slidably coupled to the spline slots **94** so that the stationary synchronizer can slide back and forth within the injection mechanism housing **14**. This allows the medication cartridge **22** to

increase the tension of the synchronizer spring **72** when the medication cartridge **22** is seated, and this increased tension causes the teeth **104** and **106** to engage.

The drive calibrator **68** is threaded onto the threaded drive shaft **76** to determine the minimum and maximum positions in which the threaded drive shaft **76** can be moved to inject medication from the medication cartridge **22**. The drive calibrator **68** also performs as a rotational reference point to keep track of the incremental movement of the threaded drive shaft **76** so that the dosage of medication injected by the pen-type injector can be accurately determined. An end of the drive calibrator **68** has splines **88** that engage corresponding spline slots **90** in the end cap **80** to hold the drive calibrator **68** in a rotationally fixed position. The other side of the end cap **80** is coupled to the medication cartridge tensioner and synchronizer **82** which is used to secure a medication cartridge **22** to the injection housing **14**. The threaded drive shaft **76** is coupled to the medication cartridge plunger **84** to inject medication in the medication cartridge **22** when the actuator knob **12** is depressed.

The illustrated direct drive mechanism only requires a single complete depression of the actuator knob **12** to inject different set amounts of medication. The illustrated direct drive allows the user to accurately set various dosage values to be injected. The drive mechanism **20** is capable of providing dosage accuracies of between 0.1 to 1.0 unit increments. However, other dosage increments may be used. Moreover, in alternative embodiments, other suitable drive mechanisms can be used by the pen-type injector such as those disclosed in U.S. Pat. No. 5,114,406 issued May 19, 1992; U.S. Pat. No. 5,226,895 issued Jul. 13, 1993; and U.S. Pat. No. 5,279,585 issued Jan. 18, 1994.

A pen-type injector **200** in accordance with an embodiment of the present invention is shown in FIGS. **14** and **15**. The pen-type injector includes a blood characteristic monitor **202**, such as a glucose meter or the like, coupled to the injection mechanism housing **14**. This pen-type injector **200**, also includes a rotatable actuator knob **12**, a medication cartridge housing **16** and a protective needle cover **26** such as those discussed above with respect to the pen-type injector **10**. Instead of a window **18**, the medication cartridge housing **16** is transparent to allow easy viewing of the medication cartridge **22**. Moreover, the clip **36** is located on the protective needle cover **26** rather than the injection mechanism housing **14**. The pen-type injector **200** also uses a microprocessor **32** and a display **34**. However, in preferred embodiments the display is larger than in the previous embodiment to display more information, and both the display and the microprocessor **32** are coupled to the blood characteristic monitor **202**. The pen-type injector **200** with the blood characteristic monitor **202** allows the user to use a single, all-in-one device that keeps records, injects medication, and determines characteristics of a blood sample.

FIG. **15** is a simplified block diagram of the pen-type injector **200** with a blood characteristic monitor **202**. The operation of the injection mechanisms and the related components is the same as described above in the previous embodiment. In the pen-type injector **202** the ROM **42** now stores additional programs to operate and control the blood characteristic monitor **202**. Moreover, the RAM **44** also stores results obtained from the blood characteristic monitor **202**. As shown in FIG. **14**, a test strip **204** for holding a blood sample is inserted into the test strip interface **206**. This activates the blood characteristic monitor **202** and the microprocessor **32**. The blood characteristic monitor **202** analyzes the blood characteristics and sends the analysis results to the microprocessor **32**, which displays the results on the display **34** and stores the results in the RAM **44** for later review.

In particular embodiments, the blood characteristic monitor **202** tests for the level of glucose in the blood. Preferably, the blood characteristic monitor **202** uses electro-chemical sensor technology (i.e., the blood sample reacts with a chemical upon the application of an electrical current). The blood characteristic monitor **202** is periodically calibrated by a reusable code strip. To perform the analysis, the blood characteristic monitor utilizes a disposable (one time use) test strip **204**. The test strip **204** utilizes capillary action at the end of the test strip to draw in a small amount of blood (typically 3 micro-liters) into a reaction chamber (not shown) in the test strip interface **206** of the blood characteristic monitor **202**. When sufficient blood has bee drawn into the reaction chamber, the test sequence begins and a blood glucose reading is displayed on the display **34** in approximately 60 seconds from the start of the testing sequence. In preferred embodiments, the blood characteristic monitor **202** provides blood glucose level results from 40–500 mg/dl (2.2–27.8 mmol/L); however, other ranges may be used.

Operation of the blood characteristic monitor **202** is relatively simple. The operator fully inserts a test strip **204** into the test strip interface **206**. This turns on the microprocessor **32** and the blood characteristic monitor **202**. In preferred embodiments, the blood analysis mode is activated and the microprocessor **32** causes the display **34** to display the previous test result and the time of the last test event. The previous time and results are alternately flashed for 5 seconds (although longer or shorter times can be used). The user then places a blood sample (usually from a finger) on the end of the inserted test strip **204**, and the capillary action in the test strip **204** draws the sample into the reaction chamber of the test strip interface **206**. In preferred embodiments, the blood characteristic monitor **202** beeps, or provides some other audible indication, when a sufficient sample has been drawn into the reaction chamber. After the beep, the test is conducted and is typically completed in about 60 seconds. Once the test is completed, the results are displayed on the display **34** and simultaneously stored by the microprocessor **32** in the RAM **44** for later recall. Removal of the test strip **204** automatically turns off the blood characteristic monitor **202** and the microprocessor **32**. If the user fails to remove the test strip **204**, the microprocessor **32** sounds an alarm, and both the blood characteristic monitor **202** and the microprocessor **32** automatically turn off after 1 minute (although other time periods may be used). In alternative embodiments, other blood characteristic monitors may be used, such as a colormetric blood glucose meter, a dry membrane chemical reaction monitor or the like. Preferred embodiments of the present invention utilize blood characteristic monitors that use electro-chemical sensor techniques developed by Miles Laboratories, Inc.

FIGS. **16**A and **16**B are a circuit schematic showing preferred embodiments of particular circuits used in the pen-type injector **200** with a blood characteristic monitor **202**.

FIGS. **17** and **18** show an alternative embodiment of a pen-type injector **250** coupled with a blood characteristic monitor **202**. The pen-type injector **250** operates in a manner similar to the embodiments described-above with respect to FIGS. **14**–**16**. However, the test strip interface **206** is 90° offset with respect to the embodiment of FIGS. **14**–**16**, and the display **34** and the mode and clock setting panel **48** are arranged differently. FIG. **18** is a cross-sectional view of the pen-type injector **250** along the line **18**—**18** shown in FIG. **17**. This view illustrates that the pen-type injector **250** can use the drive mechanism **20** described above with respect to

the embodiments of FIGS. **1–13**. Moreover, FIG. **18** illustrates the relative position of various internal components. For instance, the microprocessor **32**, the battery **50**, and a reaction chamber **252**.

FIGS. **19–21** show a preferred embodiment of a disposable needle **280** that substantially eliminates or reduces bleeding upon injection. The disposable needle **280** includes a threaded base **282**, a needle support **284**, a needle portion **286**, and a hollow cylindrical cover **288**. The threaded needle base **282** is adapted to be coupled to a pen-type injector as described above. However, in alternative embodiments, the needle base **282** may be attached by means of friction or the like, or the disposable needle **280** may be used with injectors other than pen-type injectors. A needle support **284** is coupled to the needle base **282** to hold the needle portion **286**. Also coupled to the needle support **284** and the needle base **282** is the hollow cylindrical cover **288**. The needle portion **286** is disposed inside the hollow cylindrical cover **288** such that the end of the needle portion **286** coupled to the needle support **284** cannot contact the skin during an injection. This prevents the needle support **284** from spreading the skin at the injection site. Spreading of the skin often results in bleeding. The needle portion **286** extends a sufficient distance beyond the hollow cylindrical cover **288** to allow for the proper administration of an injection. The hollow cylindrical cover helps the user insert the disposable needle **280** to the proper depth beneath the skin for an accurate injection. Moreover, the hollow cylindrical cover **288** tends to press the skin at the injection site together and this substantially eliminates or reduces bleeding at the injection site. The hollow cylindrical cover **288** also makes it easier for the user to attach and remove the disposable needle **280**, and decrease the probability of being pricked during attachment and removal of the disposable needle **280**.

FIG. **22** shows a blood characteristic monitor watch **300** in accordance with an embodiment of the present invention. The monitor watch **300** includes a blood characteristic monitor **302** and a wrist watch **304**. The blood characteristic monitor **302** is contained with the housing of the wrist watch **304** to provide a portable self-contained blood testing device that is convenient to use and can record detailed blood sample results, as well as injection administration information. This provides detailed reporting that a doctor can use to determine compliance with a prescribed medical regimen.

The wrist watch **304** resembles a conventional LCD watch, in size and shape, and includes a watch setting key pad **306**, a display **308**, and a function and power/data key pad **310** for controlling the blood characteristic monitor **302**. Inside the wrist watch **304** is a microprocessor **314** (see FIG. **23**) that couples the key pads **306** and **310** to the blood characteristic monitor **302** and the display **308**. The wrist watch **304** is secured to the user's wrist by a pair of watch straps **312**.

The blood characteristic monitor **302** includes a test strip interface **316** for receiving and analyzing a test strip **318**. The blood characteristic monitor is activated by either insertion of a test strip **318** or the power/data key pad **310**. The blood characteristic monitor **302** operates in a manner similar to that described above with respect to the embodiments of FIGS. **14–18**. The results of the blood analysis are stored by the microprocessor **314** and may be recalled for later review on the display **308**. In particular embodiments, the watch monitor **300** also includes a data input and output (I/O) port **320** which is activated and controlled by the microprocessor **314** and the power/data key pad **310** to upload program instructions and download information stored in a RAM **324** of the watch monitor **300**. In preferred embodiments, the data I/O port **320** uses infrared (IR) technology; however, other data port technologies, such as cables or the like, may be used.

FIG. **23** is a simplified block diagram of the watch monitor **300** with a blood characteristic monitor **302**. A test strip **318** is fully inserted into the test strip interface **316** to activate the blood characteristic monitor **302**. The blood characteristic monitor **302** analyzes the blood characteristics of the sample and sends the analysis results to the microprocessor **314**, which displays the results on the display **308**.

The microprocessor **314** is coupled to a ROM **322** and a RAM **324**. In preferred embodiments, the ROM **322** is an EPROM and the RAM **324** is a static RAM; however, other comparable memory storage components may be used. The ROM **322** stores the programs used by the microprocessor **314** to determine various parameters, such as the correlation of results and the deviation from preset limits in a medical regimen, the date and the time, and how to report information to the user. The RAM **324** is used by the microprocessor **314** to store information about the blood analysis, as well as injections, for later recall by the user or the doctor. The microprocessor **314** also retrieves information from the RAM **324** so that a user or doctor can transcribe the stored information at a later time to determine compliance with the medical regimen and to spot trends requiring corrective action.

In preferred embodiments, the RAM **324** has a memory capacity for over 100 blood characteristic tests, 100 injection administration events, and memory to keep track of medication scheduling and special events. The microprocessor **314** is programmed to determine trends by comparing dosages administered by injections with the blood analysis results. These trends can be used by the microprocessor **314** to automatically recommend minor changes in the dosages within pre-programmed boundaries set by the doctor, or the trend results can be used by the doctor to directly adjust the dosages boundaries and the programs utilized by the microprocessor **314**. This provides the doctor with greater control and flexibility over the user's medical regimen.

In preferred embodiments, the microprocessor **314** is coupled to a data input and output (I/O) port **320**, and the user can download the stored information to an external computer (not shown) through the data I/O port **320**. The data I/O port **320** is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor.

A clock setting key pad **306** is also coupled to the microprocessor **314** to provide the user with the capability to store additional information, set the date and the time, or set alarms on an internal clock **326** to indicate when to perform another blood analysis or administer an injection. In alternative embodiments, the microprocessor **314** may perform the internal clock functions without the necessity of a separate internal clock **326**. The function key pad **310** also provide the capability to produce detailed reports and to interface with an external computer (not shown). The key pads **306** and **310** are used in conjunction with the display **308** to access the various modes and alarms utilizing methods typically employed to set the time on an LCD watch or the like. In preferred embodiments, the internal clock **326** of the watch monitor **300** is capable of multiple daily alarms, 12/24 hour formatting, and scrolling through a time zone map for easier record keeping during time zone changes.

The watch monitor **300** also includes a self contained battery and power convertor **328**. The battery is a small

watch type battery, or in preferred embodiments, the battery is a lithium battery capable of providing power for up to 5 years.

In preferred embodiments, the blood characteristic monitor **302** analyses a blood sample to determine the level of glucose in the blood and the blood characteristic monitor **302** uses an electro-chemical sensor technology such as described above with respect to the embodiments of FIGS. **14–18**. A disposable (one time use) test strip **318** uses capillary action at the end of the test strip **318** to draw in a small amount of blood (typically 3 microliters) into a reaction chamber (not shown) of the test strip interface **316**. When sufficient blood has been drawn into the reaction chamber, the testing sequence begins and a blood glucose reading is displayed on the display **308** in approximately 60 seconds from the start of the testing sequence. The blood characteristic monitor **302** provides blood glucose results from 40–500 mg/dl (2.2–27.8 mmol/L); however, other ranges may be used.

The blood characteristic monitor **302** is operated in substantially the same manner as described above with respect to the embodiments of FIGS. **14–18**. The operator fully inserts the test strip **318** into the test strip interface **316** to turn on the blood characteristic monitor **302** and access the microprocessor **314**. The blood characteristic analysis mode is activated and the microprocessor **314** causes the display **308** to display the previous test result and the time of the last test event. The user then places a blood sample (usually from a finger) on the end of the inserted test strip **318** which draws the sample into the reaction chamber of the test strip interface **316**. In preferred embodiments, the blood monitor **302** beeps, or provides some other audible indication, when a sufficient sample has been drawn into the reaction chamber. After the beep, the test is conducted and is typically completed in about 60 seconds. Once the test is completed, the results are displayed on the display **308** and simultaneously stored by the microprocessor **314** in the RAM **324** for later recall. Removal of the test strip **318** automatically turns off the blood monitor **302** and returns the microprocessor **314** and the watch monitor **300** to the watch mode. If the user fails to remove the test strip **318**, the microprocessor **314** sounds an alarm, and the blood monitor **302** is automatically turned off after 1 minute (although other time periods may be used). In alternative embodiments, other blood characteristic monitors may be used, such as a colormetric blood glucose meter, a dry membrane chemical reaction monitor or the like. Preferred embodiments utilize the above-described electro-chemical sensor technology in sensors produced by Miles Laboratories, Inc.

FIGS. **24**(*a*)–**24**(*d*) illustrate typical reports that can be obtained via the data I/O port **320** from the watch monitor **300**. FIG. **24**(*a*) shows a summary report of the blood analysis performed by the blood characteristic monitor **302**. The readings are broken down into at least four basic time frames: breakfast, lunch, diner and snack. In preferred embodiments, the time frames may be further broken down into pre and post time frames. The report lists the number of blood analysis readings in each time frame, the standard deviation and the average value for the analyzed blood samples. FIG. **24**(*b*) shows a detailed report of all the individual blood analysis events. The report provides the date, the day, the time and the results for each analyzed blood sample. Thus, this portion of the report allows the doctor or user to spot anomalous readings. FIG. **24**(*c*) shows a detailed report on injections that have been administered and recorded by the user. The report provides the date, the day and the time of the injection. The report also recites how much of each type of insulin (regular (R) or intermediate (L)) was injected. This provides the doctor or user with information to compare blood analysis results with the amount of medication administered in the injection. FIG. **24**(*d*) shows a detailed report on markers that are set and recorded by the user to indicate certain events or changes from the regular medical regimen. This provides the doctor or user with information that can aid in understanding and correlating otherwise anomalous results.

In preferred embodiments, test results can be deleted by pressing the delete button on the function key pad **310**. This removes the results from the blood test average, for calibration or control test results, to prevent skewing the actual analysis information. The marker key on the function keypad **310** gives the user the option to store important information along with results already stored in the RAM **324**. This can aid the user in recalling specific events or types of events that establish a trend. The marks are inserted by pressing the mark key and turning the blood characteristic monitor **302** off. Markers can be used to identify meal times, exercise times, injection events, or special circumstances and changes from the normal regimen.

In alternative embodiments, the watch monitor **300** can be used with a pen-type injector **10** described in the embodiment discussed above with respect to FIGS. **1–13**. The data I/O port **320** of the watch monitor **300** can be utilized to download the injection information stored in the RAM **44** of the pen-injector **10**. This simplifies the input of relevant injection data into the watch monitor **300**.

While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. A medical injection device, comprising:

an injection mechanism including an actuator for setting the dosage and administering an injection of a medication contained within the injection device;

a processor coupled to the actuator of the injection mechanism to determine a value equal to the dosage set by the actuator of the injection mechanism; and

a memory device coupled to the processor to store the value equal to the dosage determined by the processor along with other values corresponding to previously injected dosages for later recall.

2. A device according to claim **1**, further including a receptacle capable of holding the medication, wherein the injection mechanism further includes a drive mechanism coupled between the actuator and the receptacle to inject the set dosage of the medication, and wherein the actuator of the injection mechanism triggers the drive mechanism to administer the injection of the medication held in the receptacle.

3. A device according to claim **1**, further including a display device coupled to the processor to display the value equal to the dosage determined by the processor.

4. A device according to claim **3**, further including a clock circuit coupled to the processor for determining the time, wherein the time is stored in the memory device with the

value equal to the dosage determined by the processor, and wherein the time is displayed on the display device.

5. A device according to claim 4, wherein the clock circuit further includes means to determine the date.

6. A device according to claim 4, wherein the clock circuit further includes means to provide an alarm indication at a predetermined time.

7. A device according to claim 1, further including a data port coupled to the processor that is used to transfer the value equal to the dosage stored in the memory device to an external data collection device.

8. A device according to claim 7, wherein the data port is used to transfer program instructions from an external programming device to the microprocessor.

9. A medical device, comprising:

a medication injector for injecting a dosage of a medication;

a blood characteristic monitor for analyzing a blood sample;

a processor coupled to the medication injector and the blood characteristic monitor, wherein the processor determines a value equal to the dosage of the medication to be injected by the medication injector, and wherein the processor determines blood characteristics from the blood sample analyzed by the blood characteristic monitor.

10. A device according to claim 9, further including a memory device coupled to the processor to store the value equal to the dosage and the blood characteristics determined by the processor.

11. A device according to claim 10, further including a receptacle capable of holding the medication and an injection mechanism having an actuator knob for setting the dosage of the medication to be administered by the medication injector and a drive mechanism coupled between the actuator knob and the receptacle to inject the set dosage of the medication, wherein the actuator knob of the injection mechanism triggers the drive mechanism to administer the injection of the medication held in the receptacle.

12. A device according to claim 10, further including a display device coupled to the processor to display the value equal to the dosage and the blood characteristics determined by the processor.

13. A device according to claim 12, further including a clock circuit coupled to the processor for determining a time, wherein the time is stored in the memory device with the value equal to the dosage and the blood characteristics determined by the processor, and wherein the time is displayed on the display device.

14. A device according to claim 13, wherein the clock circuit further includes means to determine the date.

15. A device according to claim 13, wherein the clock circuit further include means to provide an alarm indication at a predetermined time.

16. A device according to claim 10, further including a data port coupled to the processor that is used to transfer the value equal to the dosage stored in the memory device to an external data collection device.

17. A device according to claim 9, further including a data port coupled to the processor that is used to transfer program instructions from an external programming device to the processor.

18. A device according to claim 9, further including a clock and a memory storage device coupled to the processor for storing a measure of time from the clock and the blood characteristics determined by the processor.

19. A device according to claim 18, further including a display device coupled to the processor to display the measure of the time from the clock and the blood characteristics determined by the processor.

20. A device according to claim 18, further including a data port coupled to the processor that is used to transfer the measure of the time and the blood characteristics stored in the memory device to an external data collection device.

21. A device according to claim 20, wherein the data port uses infrared energy to transfer the measure of the time and the blood characteristics stored in the memory storage device.

22. A device according to claim 9, further including a data port coupled to the processor that is used to transfer program instructions from an external programing device to the processor.

23. A device according to claim 22, wherein the data port uses infrared energy to transfer the program instructions.

24. A portable blood monitor, comprising:

a housing sized and adapted to be worn on a wrist;

a clock contained in the housing for measuring time;

a blood characteristic monitor contained in the housing for analyzing a blood sample; and

a processor coupled to the blood characteristic monitor and the clock, wherein the processor determines blood characteristics based on the analyzed blood sample from the blood characteristic monitor, and wherein the processor uses the measure of the time from the clock to identify when the blood characteristics were determined.

25. A monitor according to claim 24, further including a memory storage device coupled to the processor for storing the measure of time from the clock and the blood characteristics determined by the processor.

26. A monitor according to claim 25, further including a display device coupled to the processor to display the measure of the time from the clock and the blood level characteristics determined by the processor.

27. A monitor according to claim 25, further including a data port coupled to the processor that is used to transfer measure of the time and the blood characteristics stored in the memory device to an external data collection device.

28. A monitor according to claim 24, wherein the clock circuit further includes means to determine the date.

29. A monitor according to claim 24, wherein the clock circuit further includes means to provide an alarm indication at a predetermined time.

30. A monitor according to claim 24, further including a data port coupled to the processor that is used to transfer program instructions from an external programming device to the processor.

31. A monitor according to claim 30, wherein the data port uses infrared energy to transfer the measure of the time and the blood characteristics.

32. A monitor according to claim 30, wherein the data port uses infrared energy to transfer the program instructions.

33. A portable medical device to maintain and monitor a condition of an individual's body, the device comprising:

an injector for injecting a dosage of an injectable substance into the individual's body;

a characteristic monitor for analyzing a fluid sample consisting of saliva, urine or blood removed from the individual's body;

a processor coupled to the injector and the characteristic monitor, wherein the processor determines a value equal to the dosage of the injectable substance to be injected by the injector into the individual's body, and wherein the processor determines sample characteris-

tics from the sample analyzed by the characteristic monitor.

34. A device according to claim **33**, further including a memory device coupled to the processor to store the value equal to the dosage and the sample characteristics determined by the processor.

35. A device according to claim **34**, further including a receptacle capable of holding the injectable substance and an injection mechanism having an actuator knob for setting the dosage of the injectable substance to be administered by the injector and a drive mechanism coupled between the actuator knob and the receptacle to inject the set dosage of the injectable substance, wherein the actuator knob of the injection mechanism triggers the drive mechanism to administer the injection of the injectable substance held in the receptacle.

36. A device according to claim **34**, further including a display device coupled to the processor to display the value equal to the dosage and the sample characteristics determined by the processor.

37. A device according to claim **36**, further including a clock circuit coupled to the processor for determining a time, wherein the time is stored in the memory device with the value equal to the dosage and the sample characteristics determined by the processor, and wherein the time is displayed on the display device.

38. A device according to claim **37**, wherein the clock circuit further includes means to determine the date.

39. A device according to claim **37**, wherein the clock circuit further includes means to provide an alarm indication at a predetermined time.

40. A device according to claim **34**, further including a data port coupled to the processor that: is used to transfer the value equal to the dosage stored in the memory device to an external data collection device.

41. A device according to claim **33**, further including a data port coupled to the processor that is used to transfer program instructions from an external programming device to the processor.

42. A device according to claim **33**, further including a clock and a memory storage device coupled to the processor for storing a measure of time from the clock and the sample characteristics determined by the processor.

43. A device according to claim **42**, further including a display device coupled to the processor to display the measure of the time from the clock and the sample characteristics determined by the processor.

44. A device according to claim **42**, further including a data port coupled to the processor that is used to transfer the measure of the time and the sample characteristics stored in the memory device to an external data collection device.

45. A device according to claim **44**, wherein the data port uses infrared energy to transfer the measure of the time and the sample characteristics stored in the memory device.

46. A device according to claim **33**, further including a data port coupled to the processor that is used to transfer program instructions from an external programming device to the processor.

47. A device according to claim **46**, wherein the data port uses infrared energy to transfer the program instructions.

48. A method of maintaining and monitoring a condition of an individual's body with a portable medical device, the method comprising the steps of:

determining a value equal to a dosage of an injectable substance to be injected into the individual's body using a processor in the medical device;

injecting a dosage of a the injectable substance into the individual's body using an injector in the medical device;

removing a fluid sample consisting of saliva, urine or blood removed from the individuals body;

analyzing a sample with a characteristic monitor in the medical device;

determining sample characteristics from the sample analyzed by the characteristic monitor with the processor in the medical device.

49. A method according to claim **48**, further including the step of transferring program instructions from an external programming device to the processor.

50. A method according to claim **48**, further including the step of storing the value equal to the dosage and the sample characteristics determined by the processor in a memory device.

51. A method according to claim **50**, further including the step of transferring the value equal to the dosage stored in the memory device to an external data collection device.

52. A method according to claim **50**, further including the step of displaying the value equal to the dosage and the sample characteristics determined by the processor.

53. A method according to claim **52**, further including the steps of:

determining a time;

storing the time in the memory device with the value equal to the dosage and the sample characteristics determined by the processor; and

displaying the time.

54. A method according to claim **53**, further including the step of determining the date.

55. A method according to claim **54**, further including the step of providing an alarm indication at a predetermined time.

* * * * *

US005536249C1

(12) **EX PARTE REEXAMINATION CERTIFICATE** (5929th)

United States Patent

Castellano et al.

(10) **Number: US 5,536,249 C1**

(45) **Certificate Issued: *Oct. 9, 2007**

(54) **PEN-TYPE INJECTOR WITH A MICROPROCESSOR AND BLOOD CHARACTERISTIC MONITOR**

(75) Inventors: **Thomas P. Castellano**, Los Angeles, CA (US); **Robert Schumacher**, Beverly Hills, CA (US)

(73) Assignee: **Visionary Medical Products, Inc.**, Los Angeles, CA (US)

Reexamination Request:
No. 90/007,547, May 18, 2005

Reexamination Certificate for:
Patent No.: **5,536,249**
Issued: **Jul. 16, 1996**
Appl. No.: **08/208,636**
Filed: **Mar. 9, 1994**

(*) Notice: This patent is subject to a terminal disclaimer.

(51) **Int. Cl.**
A61M 31/00 (2006.01)

(52) **U.S. Cl.** **604/65**; 128/DIG. 1

(58) **Field of Classification Search** 604/65
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,997,129	A	4/1935	Taylor et al.	
2,221,739	A	11/1940	Reiter	
2,605,763	A	8/1952	Smoot	
2,632,445	A	3/1953	Kas	
2,695,023	A	11/1954	Brown	
2,718,299	A	9/1955	Atwater et al.	
3,110,310	A	11/1963	Cislak	
3,141,583	A	7/1964	Mapel et al.	
3,293,749	A	12/1966	George et al.	
3,348,545	A	10/1967	Sarnoff et al.	
3,481,510	A	12/1969	Allen, Jr.	
3,517,668	A	6/1970	Brickson	
3,583,399	A	6/1971	Ritsky	
3,894,683	A	7/1975	Carhart et al.	
3,923,060	A	12/1975	Ellinwood, Jr.	128/260

(Continued)

FOREIGN PATENT DOCUMENTS

CA	1103314	6/1981
CH	1293302	9/1953
DE	730971	12/1942
DE	70784	12/1959
DE	22140	10/1961
DE	3824217	1/1990
EP	0 037 696	10/1981
EP	0 058 536	8/1982
EP	0098592	7/1983
EP	0 143 895	6/1985

(Continued)

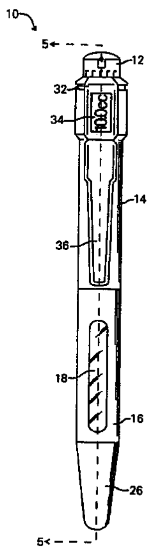
OTHER PUBLICATIONS

Opposition to European Patent No. 749,332, filed on behalf of Novo Nordisk A/S and communicated to the patentee Apr. 4, 2006.

Primary Examiner—Beverly M. Flanagan

(57) **ABSTRACT**

A medical injection device, such as a pen-type injector has a microprocessor coupled to the injector that records the date, the time, and the amount of each injection. The microprocessor may also be coupled to a display to indicate the amount of medication to be injected. The medical injection device can also be coupled with a blood characteristic monitor to analyze characteristics of the blood. This provides a single, all-in-one device that performs a variety of functions, and requires only a minimum of space. The medical injection device may also use a disposable needle that substantially eliminates or reduces bleeding from an opening in the skin at the injection site.



U.S. PATENT DOCUMENTS

3,977,574	A		8/1976	Thomas	
4,003,379	A		1/1977	Ellinwood, Jr.	128/260
4,022,207	A		5/1977	Citrin	
4,099,548	A		7/1978	Sturm et al.	
4,146,029	A		3/1979	Ellinwood, Jr.	128/260
4,333,458	A		6/1982	Margulies et al.	
4,395,921	A		8/1983	Oppenlander	
4,413,760	A		11/1983	Paton	
4,415,101	A		11/1983	Shapiro et al.	
4,425,121	A		1/1984	Young et al.	
4,435,173	A		3/1984	Siposs et al.	
4,444,560	A		4/1984	Jacklich	
4,457,712	A		7/1984	Dragan	
4,470,317	A		9/1984	Sabloewski et al.	
4,475,905	A		10/1984	Himmelstrup	
4,498,904	A		2/1985	Turner et al.	
4,526,294	A		7/1985	Hirschmann et al.	
4,526,569	A		7/1985	Bernardi	604/4
4,529,401	A		7/1985	Leslie et al.	
4,581,022	A		4/1986	Leonard et al.	
4,592,745	A		6/1986	Rex et al.	
4,627,445	A		12/1986	Garcia et al.	128/770
4,633,878	A		1/1987	Bombardieri	128/635
4,659,327	A		4/1987	Bennett et al.	
4,664,128	A		5/1987	Lee	
4,710,172	A		12/1987	Jacklich et al.	
4,710,178	A		12/1987	Henri et al.	
4,731,726	A		3/1988	Allen, III	364/416
4,820,287	A		4/1989	Leonard	
4,865,591	A		9/1989	Sams	
4,883,472	A		11/1989	Michel	
4,936,833	A		6/1990	Sams	
4,950,246	A		8/1990	Muller	
4,953,552	A		9/1990	DeMarzo	128/635
4,959,056	A		9/1990	Dombrowski et al.	
4,959,196	A		9/1990	Moisson	422/82.05
4,998,570	A		3/1991	Strong	
5,024,656	A		6/1991	Gasaway et al.	
5,050,612	A	*	9/1991	Matsumura	600/483
5,069,668	A		12/1991	Boydman	
5,085,642	A		2/1992	Sarnoff et al.	
5,092,842	A		3/1992	Bechtold et al.	
5,097,834	A		3/1992	Skrabal	128/632
5,102,393	A		4/1992	Sarnoff et al.	
5,104,380	A		4/1992	Holman et al.	
5,112,317	A		5/1992	Michel	
5,114,406	A		5/1992	Gabriel et al.	
5,139,484	A		8/1992	Hazon et al.	
5,176,632	A		1/1993	Bernardi	604/66
5,180,371	A		1/1993	Spinello	
5,226,895	A		7/1993	Harris	
5,226,896	A		7/1993	Harris	
5,243,982	A		9/1993	Mostl et al.	128/632
5,244,461	A		9/1993	Derlien	
5,244,465	A		9/1993	Michel	
5,279,585	A		1/1994	Balkwill	
5,279,586	A		1/1994	Balkwill	
5,343,869	A	*	9/1994	Pross et al.	600/301
5,364,346	A		11/1994	Schrezenmeir	604/50
5,383,865	A		1/1995	Michel	
5,497,772	A	*	3/1996	Schulman et al.	600/347
5,522,805	A	*	6/1996	Vancaillie et al.	604/246
5,593,390	A	*	1/1997	Castellano et al.	604/187
5,728,074	A	*	3/1998	Castellano et al.	604/207
5,925,021	A	*	7/1999	Castellano et al.	604/207

FOREIGN PATENT DOCUMENTS

EP	0 416 975	3/1991
EP	0 225 137	6/1991
EP	0 249 687	6/1993
FR	1 149 735	12/1957
FR	1 170 312	1/1959
FR	1 445 659	6/1966
FR	2 148 642	9/1979
FR	2 557 445	5/1985
GB	1 225 495	3/1971
GB	1574267	9/1980
GB	2 109 690	2/1982
JP	5-49696	3/1993
WO	WO 85/02546	6/1985
WO	WO 86/01728	3/1986
WO	92/13583	8/1992
WO	87/03814	7/1998
WO	88/05643	8/1998

* cited by examiner

EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims **1**, **7**, **9**, **22**, **24**, **33**, and **48** are determined to be patentable as amended.

Claims **2**–**6**, **8**, **10**–**21**, **23**, **25**–**32**, **34**–**47**, and **49**–**55** dependent on an amended claim, are determined to be patentable.

1. A *pen-type* medical injection device, comprising *in a single hand held housing*:

an injection mechanism including an actuator *manipulated by the user* for setting the dosage and administering an injection of a medication contained within the injection device;

a processor coupled to the actuator of the injection mechanism to determine a value equal to the dosage set by the actuator of the injection mechanism; and

a memory device coupled to the processor to store the value equal to the dosage determined by the processor along with other values corresponding to previously injected dosages for later recall.

7. A device according to claim **1**, further including a data port coupled to the processor that is used to transfer the *numerical* value equal to the dosage stored in the memory device to an external data collection device.

9. A medical device, comprising:

a medication injector for injecting a dosage of a medication;

a blood characteristic monitor for analyzing a *non-perfusate* blood sample;

a processor coupled to the medication injector and the blood characteristic monitor, wherein the processor determines a value equal to the dosage of the medication to be injected by the medication injector, and wherein the processor determines blood characteristics from the *non-perfusate* blood sample analyzed by the blood characteristic monitor.

22. A device according to claim **9**, further including a data port coupled to the processor that is used to transfer program instructions from an external **[**programing**]** *programming* device to the processor.

24. A portable blood monitor, comprising:

a housing sized and adapted to be worn on a wrist;

a clock contained in the housing for measuring time;

a blood characteristic monitor contained in the housing for analyzing a *non-perfusate* blood sample; and

a processor coupled to the blood characteristic monitor and the clock, wherein the processor determines blood characteristics based on the analyzed *non-perfusate* blood sample from the blood characteristic monitor, and wherein the processor uses the measure of the time from the clock to identify when the blood characteristics were determined.

33. A portable medical device to maintain and monitor a condition of an individual's body, the device comprising:

an injector for injecting a dosage of an injectable substance into the individual's body;

a characteristic monitor for analyzing a *non-perfusate* fluid sample consisting of **[**saliva, urine or**]** blood removed from the individual's body;

a processor coupled to the injector and the characteristic monitor, wherein the processor determines a value equal to the dosage of the injectable substance to be injected by the injector into the individual's body, and wherein the processor determines sample characteristics from the *non-perfusate* sample analyzed by the characteristic monitor.

48. A method of maintaining and monitoring a condition of an individual's body with a portable medical device, the method comprising the steps of:

determining a value equal to a dosage of an injectable substance to be injected into the individual's body using a processor in the medical device;

injecting a dosage of **[**a**]** the injectable substance into the individual's body using an injector in the medical device;

removing a *non-perfusate* fluid sample consisting of **[**saliva, urine or**]** blood removed from the individuals body;

analyzing **[**a**]** *the non-perfusate* sample with a characteristic monitor in the medical device;

determining sample characteristics from the *non-perfusate* sample analyzed by the characteristic monitor with the processor in the medical device.

* * * * *

EXHIBIT B

US005925021A

United States Patent [19]

Castellano et al.

[11] Patent Number: 5,925,021

[45] Date of Patent: Jul. 20, 1999

[54] **MEDICATION DELIVERY DEVICE WITH A MICROPROCESSOR AND CHARACTERISTIC MONITOR**

[75] Inventors: **Thomas P. Castellano**; **Robert Schumacher**, both of Beverly Hills, Calif.

[73] Assignee: **Visionary Medical Products, Inc.**, Los Angeles, Calif.

[21] Appl. No.: **08/899,764**

[22] Filed: **Jul. 24, 1997**

Related U.S. Application Data

[63] Continuation of application No. 08/782,541, Jan. 10, 1997, is a continuation of application No. 08/396,420, Feb. 28, 1995, Pat. No. 5,593,390, which is a continuation-in-part of application No. 08/350,405, Dec. 5, 1994, Pat. No. 5,728,074, which is a continuation-in-part of application No. 08/208,636, Mar. 9, 1994, Pat. No. 5,536,249.

[51] **Int. Cl.**^{6} **A61M 5/00**

[52] **U.S. Cl.** **604/207**; 600/322; 600/309

[58] **Field of Search** 600/300, 308, 600/310, 309, 322, 345, 367, 368, 583, 301; 604/65–67, 31, 246, 260, 207; 128/DIG. 1

[56] **References Cited**

U.S. PATENT DOCUMENTS

1,997,129	4/1935	Taylor et al. .
2,221,739	11/1940	Reiter .
2,605,763	8/1952	Smoot .
2,632,445	3/1953	Kas .
2,695,023	11/1954	Brown .
2,718,299	9/1955	Atwater et al. .
3,110,310	11/1963	Cislak .
3,141,583	7/1964	Mapel et al. .
3,293,749	12/1966	George et al. .
3,348,545	10/1967	Sarnoff et al. .
3,481,510	12/1969	Allen, Jr. .
3,517,668	6/1970	Brickson .
3,583,399	6/1971	Ritsky .
3,894,663	7/1975	Carhart et al. .
3,977,574	8/1976	Thomas .
4,022,207	5/1977	Citrin .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

55604/86	10/1987	Australia .
1103314	6/1981	Canada .
91225137	of 0000	European Pat. Off. .

(List continued on next page.)

OTHER PUBLICATIONS

PCT Written Opinion issued by the European Patent Office on Nov. 3, 1995.

Search Report for PCT/US95/01727, mailed Jun. 20, 1995[4].

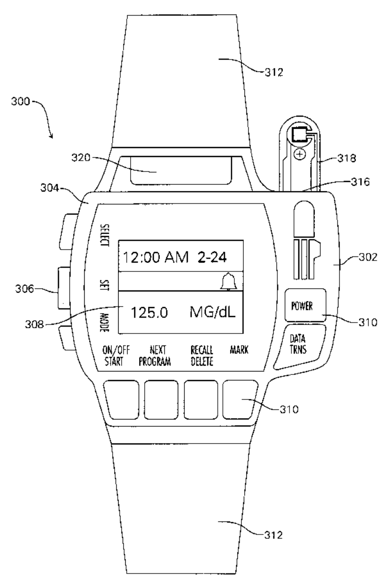
Annual International Conference of the IEEE Engineering in Medicine and Biology Society, "An Optical and RF Telemetry Drug Injection Control and ECG System for Awake Small Animal Studies", vol. 13, No. 5, 1991.

Primary Examiner—Ronald Stright
Assistant Examiner—A. T. Nguyen
Attorney, Agent, or Firm—Pillsbury Madison & Sutro LLP

[57] **ABSTRACT**

A medication delivery device, such as a pen-type injector, jet injector, medication pump, inhaler, spray or the like has a microprocessor coupled to the device that records the date, the time, and the amount of each medication administration. The microprocessor may also be coupled to a display to indicate the amount of medication to be administered. The medication delivery device can also be coupled with a blood characteristic monitor to analyze characteristics of the blood. This provides a single, all-in-one device that performs a variety of functions, and requires only a minimum of space. The medication delivery device may also use a disposable needle that substantially eliminates or reduces bleeding from an opening in the skin at the injection site.

28 Claims, 26 Drawing Sheets



U.S. PATENT DOCUMENTS

4,099,548	7/1978	Sturm et al. .
4,114,619	9/1978	Wagner .
4,139,008	2/1979	Wagner .
4,146,029	3/1979	Ellinwood, Jr. .
4,169,474	10/1979	Wagner .
4,284,077	8/1981	Wagner .
4,333,458	6/1982	Margulies et al. .
4,393,870	7/1983	Wagner .
4,395,921	8/1983	Oppenlander .
4,413,760	11/1983	Paton .
4,415,101	11/1983	Shapiro et al. .
4,425,121	1/1984	Young et al. .
4,435,173	3/1984	Siposs et al. .
4,444,560	4/1984	Jacklich .
4,457,712	7/1984	Dragan .
4,470,317	9/1984	Sabloewski et al. .
4,475,905	10/1984	Himmelstrup .
4,498,904	2/1985	Turner et al. .
4,526,294	7/1985	Hirschmann et al. .
4,529,401	7/1985	Leslie et al. .
4,573,970	3/1986	Wagner .
4,581,022	4/1986	Leonard et al. .
4,592,745	6/1986	Rex et al. .
4,600,403	7/1986	Wagner .
4,659,327	4/1987	Bennett et al. .
4,664,128	5/1987	Lee .
4,710,172	12/1987	Jacklich et al. .
4,710,178	12/1987	Leonard et al. .
4,820,287	4/1989	Leonard .
4,865,591	9/1989	Sams .
4,883,472	11/1989	Michel .
4,936,833	6/1990	Sams .
4,950,246	8/1990	Muller .
4,959,056	9/1990	Dombrowski et al. .
4,998,570	3/1991	Strong .
5,024,656	6/1991	Gasaway et al. .
5,047,044	9/1991	Smith et al. .
5,069,668	12/1991	Boydman .
5,085,642	2/1992	Sarnoff et al. .
5,092,842	3/1992	Bechtold et al. .
5,102,393	4/1992	Sarnoff et al. .
5,104,380	4/1992	Holman et al. .
5,112,317	5/1992	Michel .
5,114,406	5/1992	Gabriel et al. .
5,139,484	8/1992	Hazon et al. .
5,180,371	1/1993	Spinello .
5,226,895	7/1993	Harris .
5,226,896	7/1993	Harris .
5,244,461	9/1993	Derlien .
5,244,465	9/1993	Michel .
5,256,157	10/1993	Samiotes et al. .
5,279,585	1/1994	Balkwill .
5,279,586	1/1994	Balkwill .
5,383,865	1/1995	Michel .
5,425,716	6/1995	Kawasaki et al. .
5,429,602	7/1995	Hauser .
5,509,905	4/1996	Michel .

FOREIGN PATENT DOCUMENTS

93249687	of 0000	European Pat. Off. .
0037696	10/1981	European Pat. Off. .
0058536	8/1982	European Pat. Off. .
0143895	6/1985	European Pat. Off. .
0327910	8/1989	European Pat. Off. .
0368191	5/1990	European Pat. Off. .
0416975	3/1991	European Pat. Off. .
1149735	12/1957	France .
1170312	1/1959	France .
1445659	6/1966	France .
2418642	9/1979	France .
2557445	5/1985	France .
730971	12/1942	Germany .
1070784	12/1959	Germany .
22140	10/1961	Germany .
293302	9/1953	Switzerland .
1225495	3/1971	United Kingdom .
1574267	9/1980	United Kingdom .
2109690	2/1982	United Kingdom .
WO8502546	6/1985	WIPO .
8601728	3/1986	WIPO .
9213583	8/1992	WIPO .
WO9310838	6/1993	WIPO .
WO9524233	9/1995	WIPO .

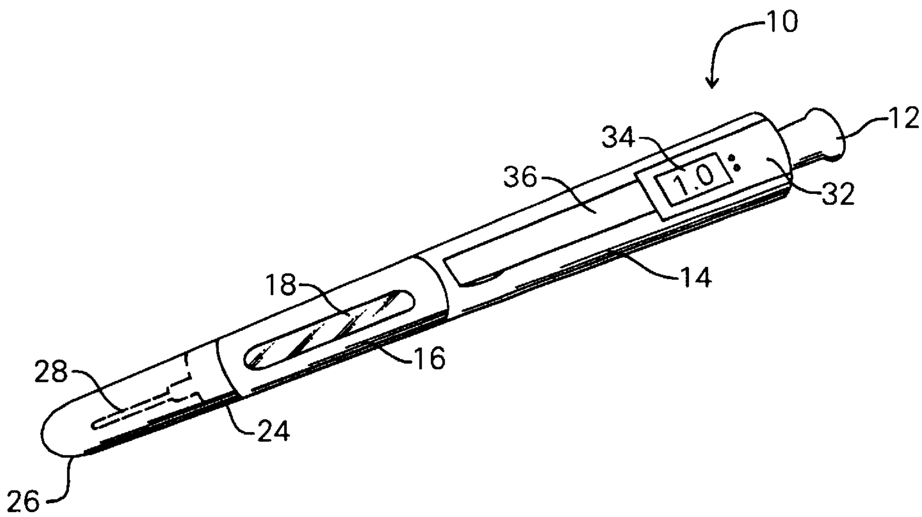

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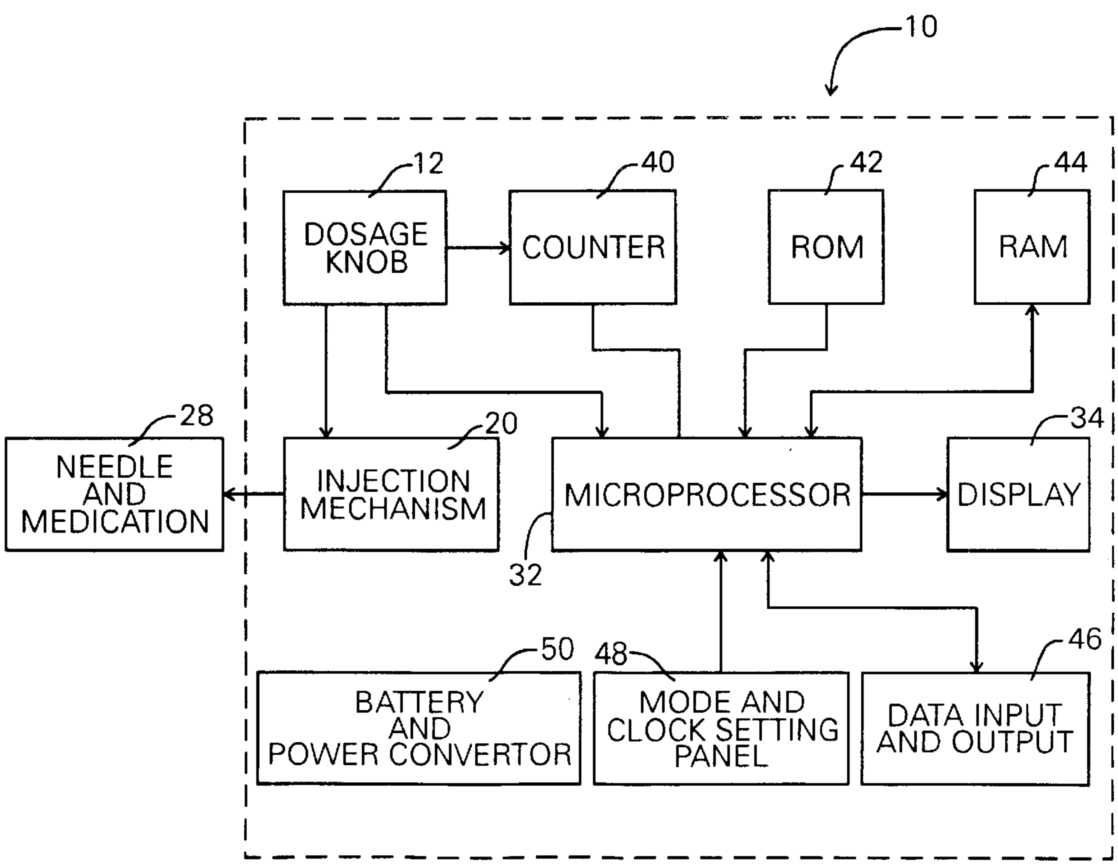
FIG. 1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DISPLAY
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BATTERY AND POWER CONVERTOR
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MODE AND CLOCK SETTING PANEL
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DATA INPUT AND OUTPUT

FIG. 4

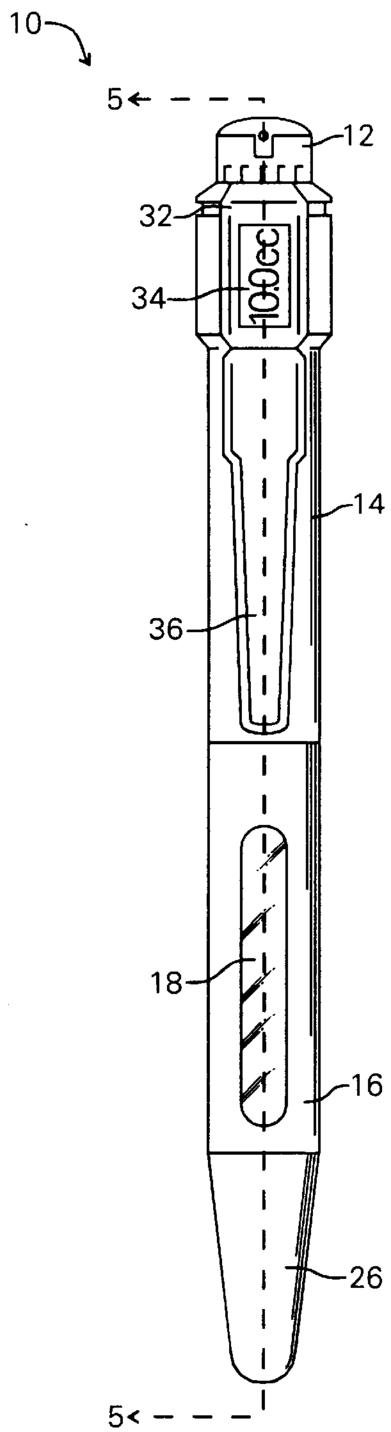
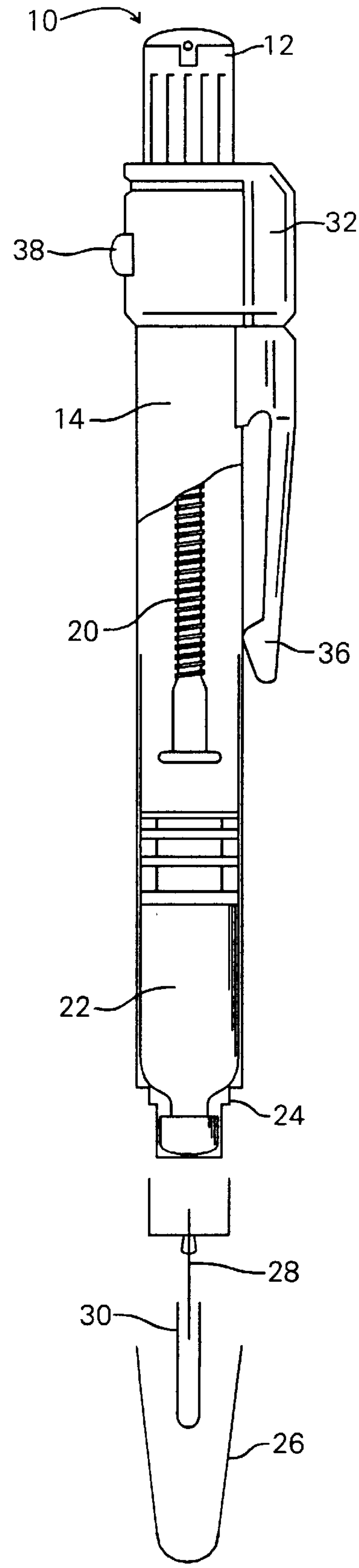


FIG. 2



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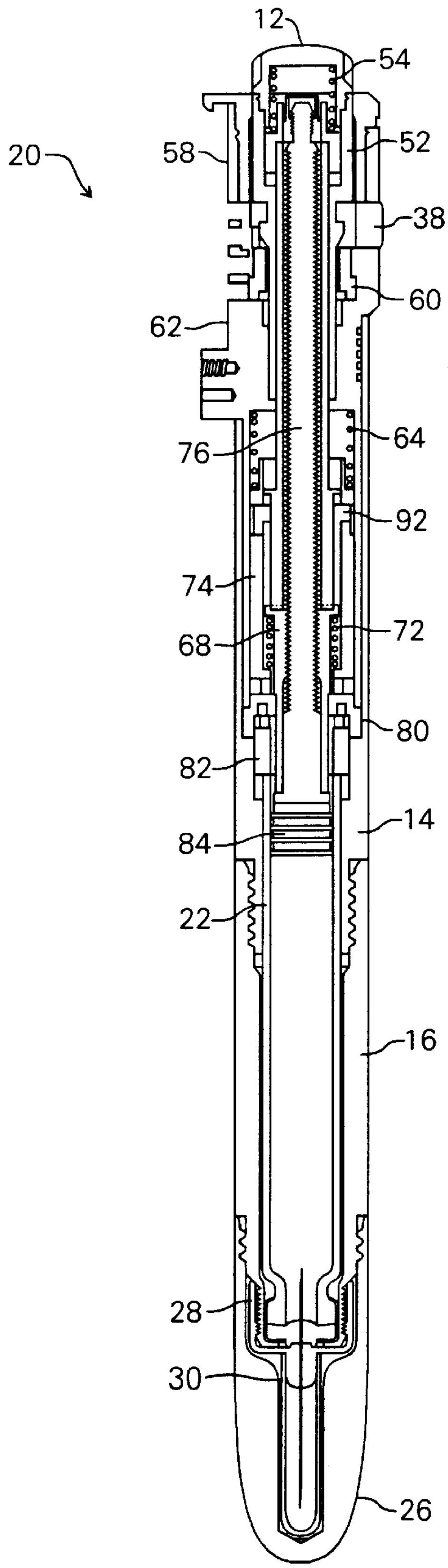
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FIG. 5

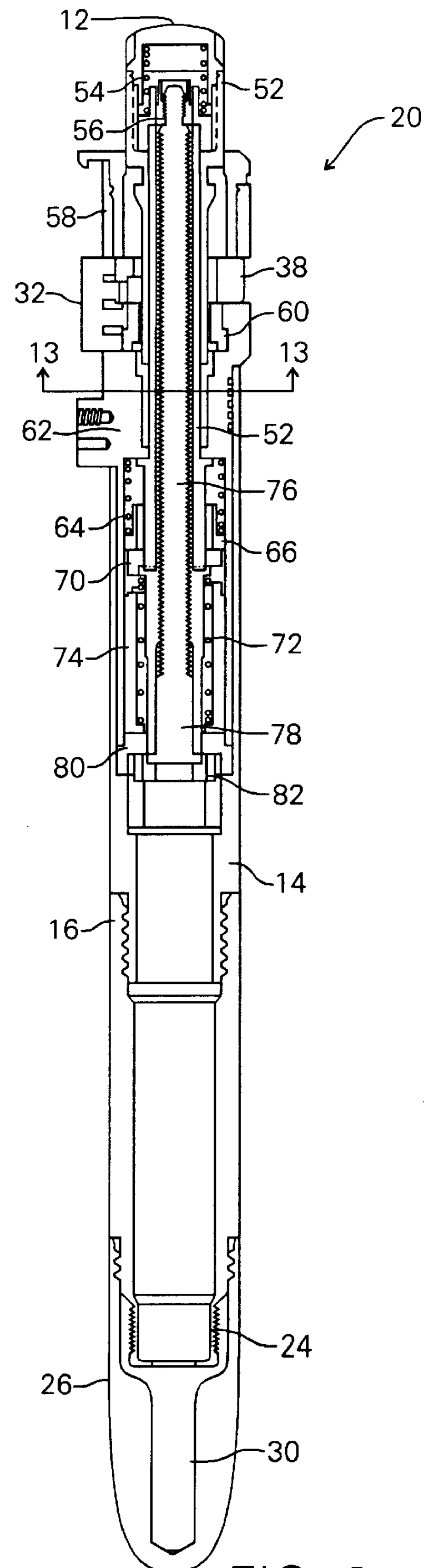
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FIG. 6

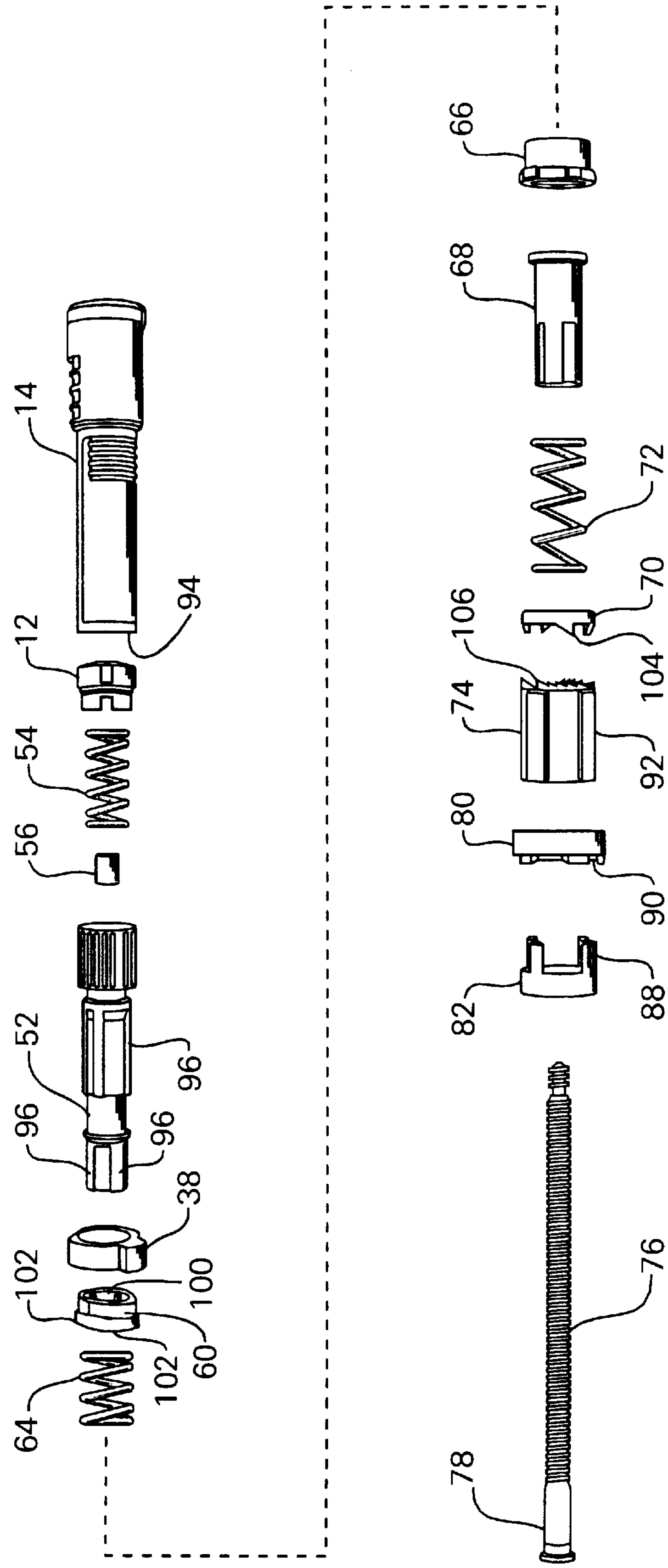
14
12
94
54
56
52
96
96
96
38
102
100
102
60
64
66
68
72
70
106
104
74
92
80
90
82
88
76
78

FIG. 7(a)

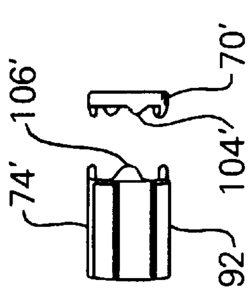

FIG. 7(b)

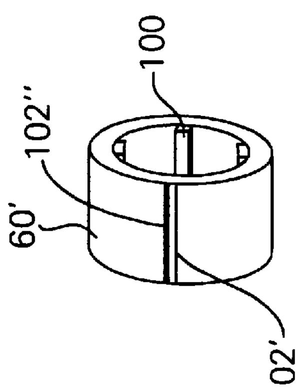

FIG. 7(c)

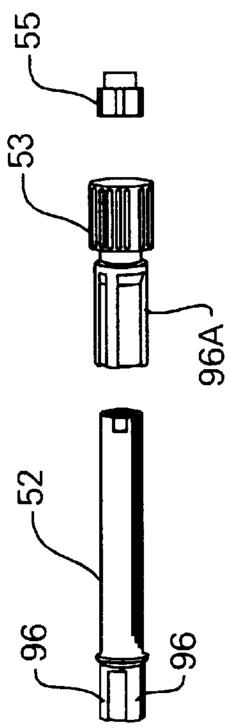

FIG. 7(d)

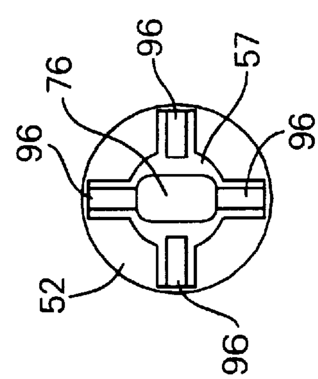

FIG. 7(e)

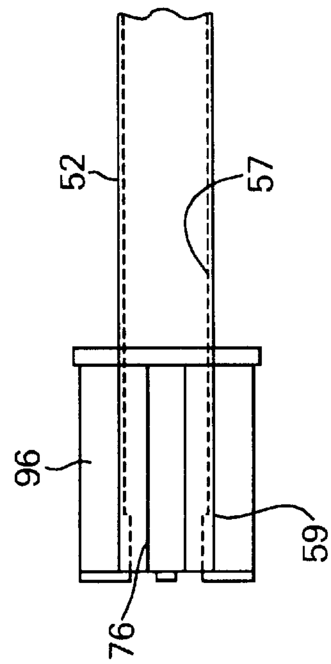

FIG. 7(f)

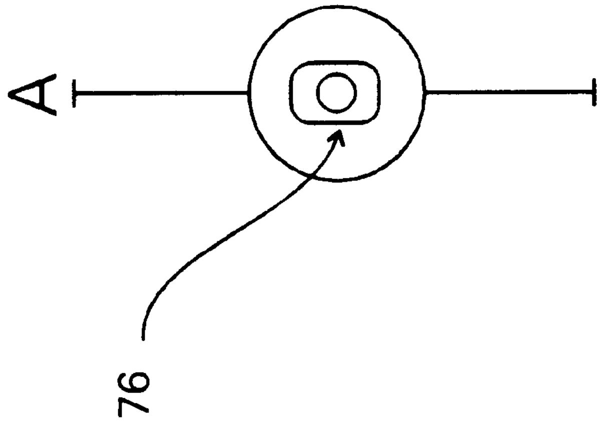

Fig. 7(h)

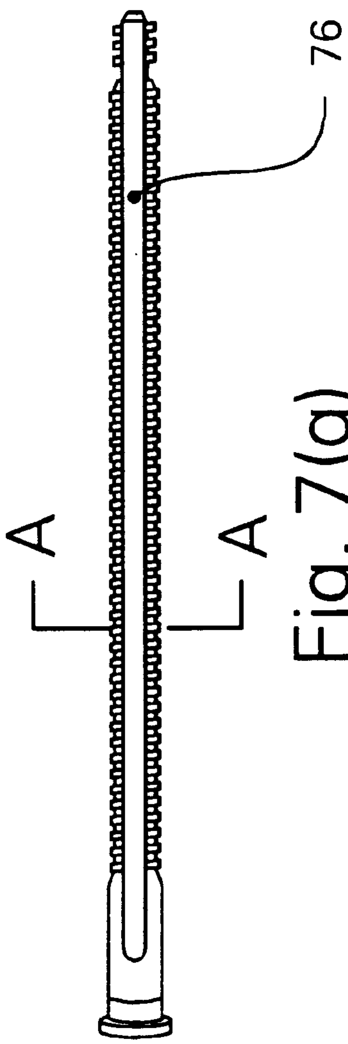

Fig. 7(g)

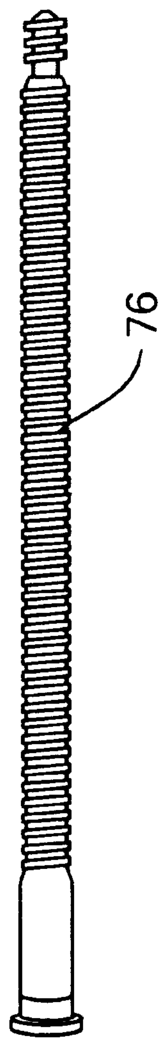

Fig. 7(i)

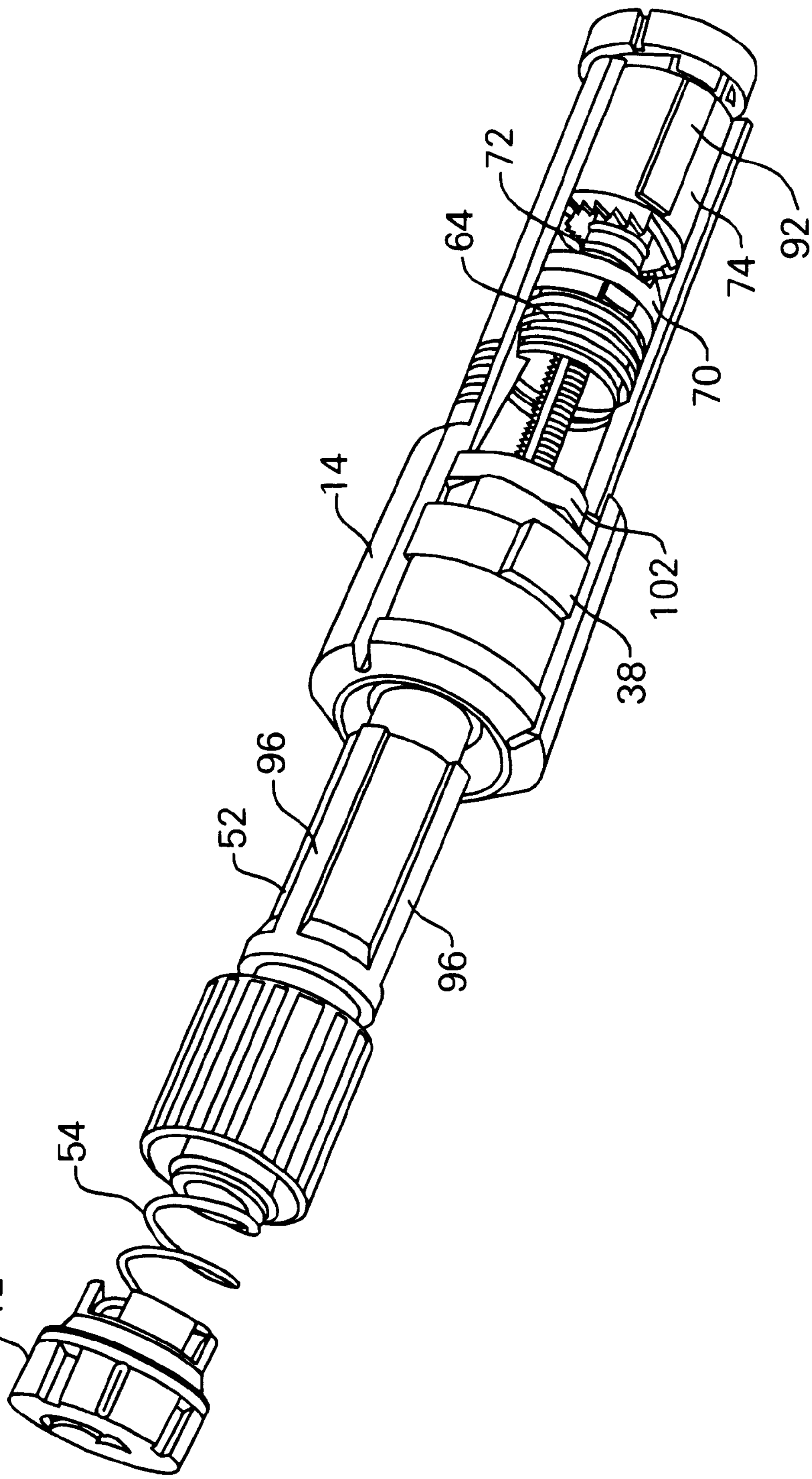

FIG. 8

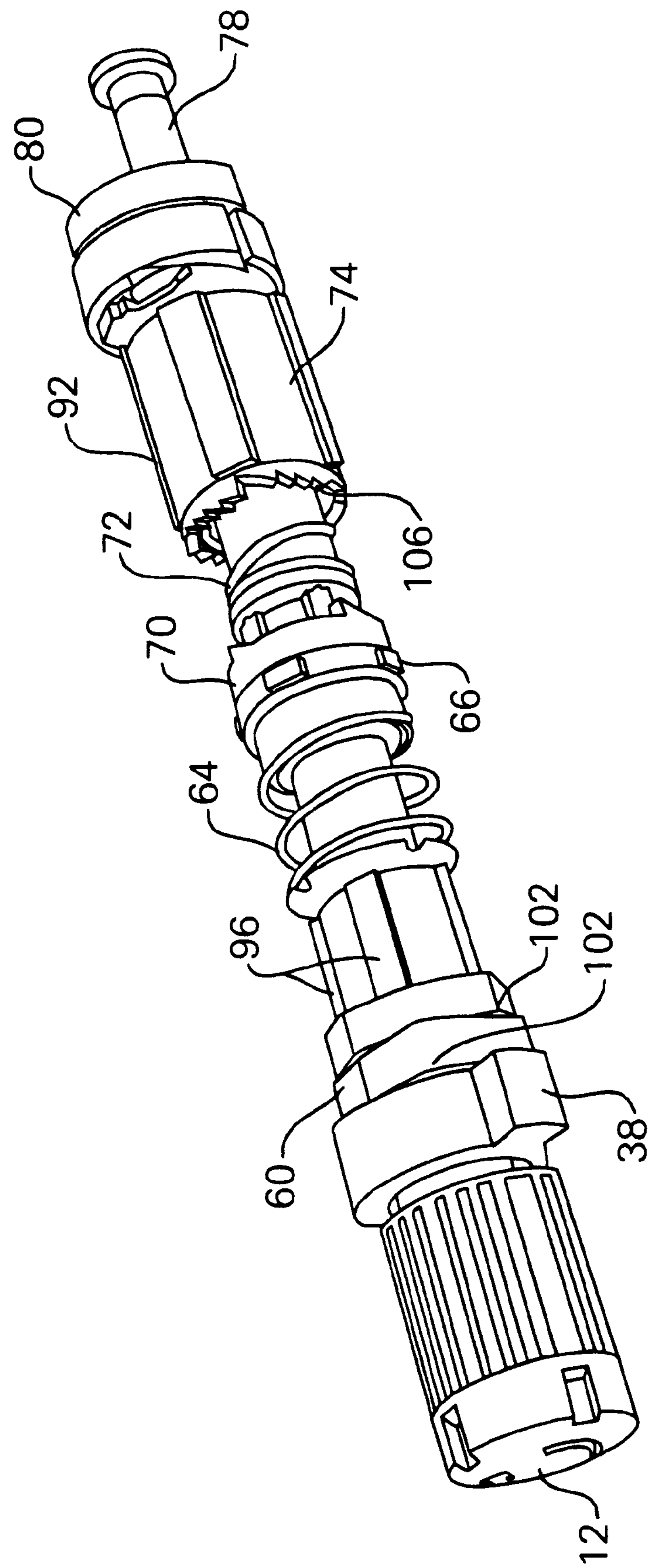

FIG. 9

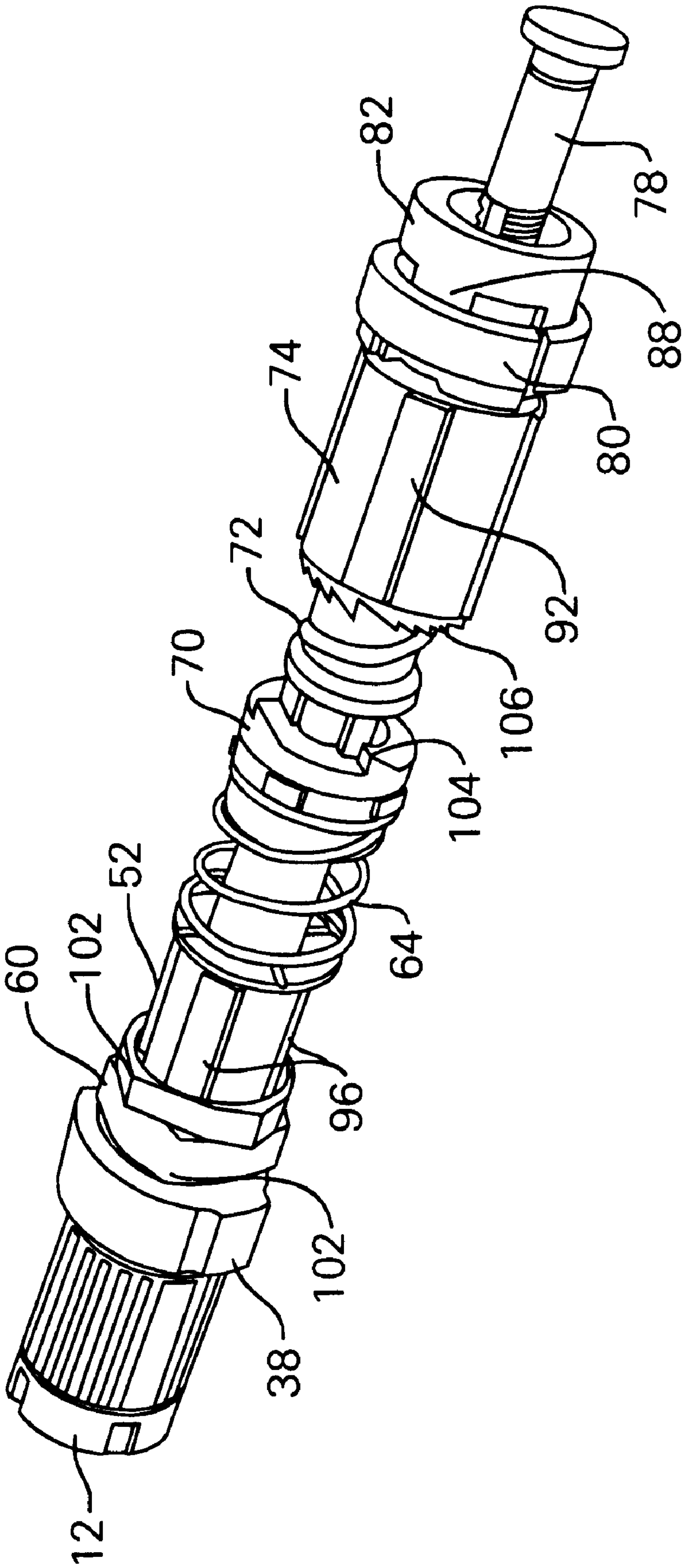

FIG. 10

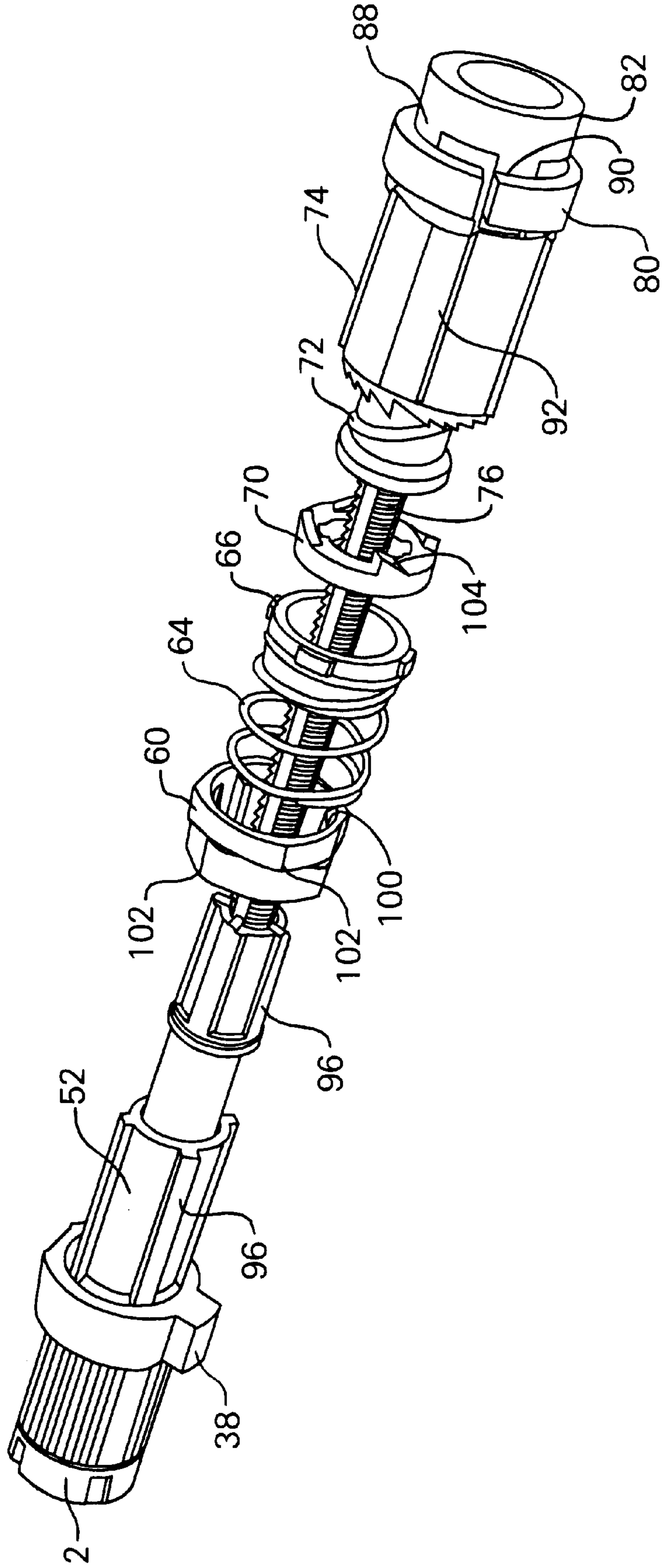

FIG. 11

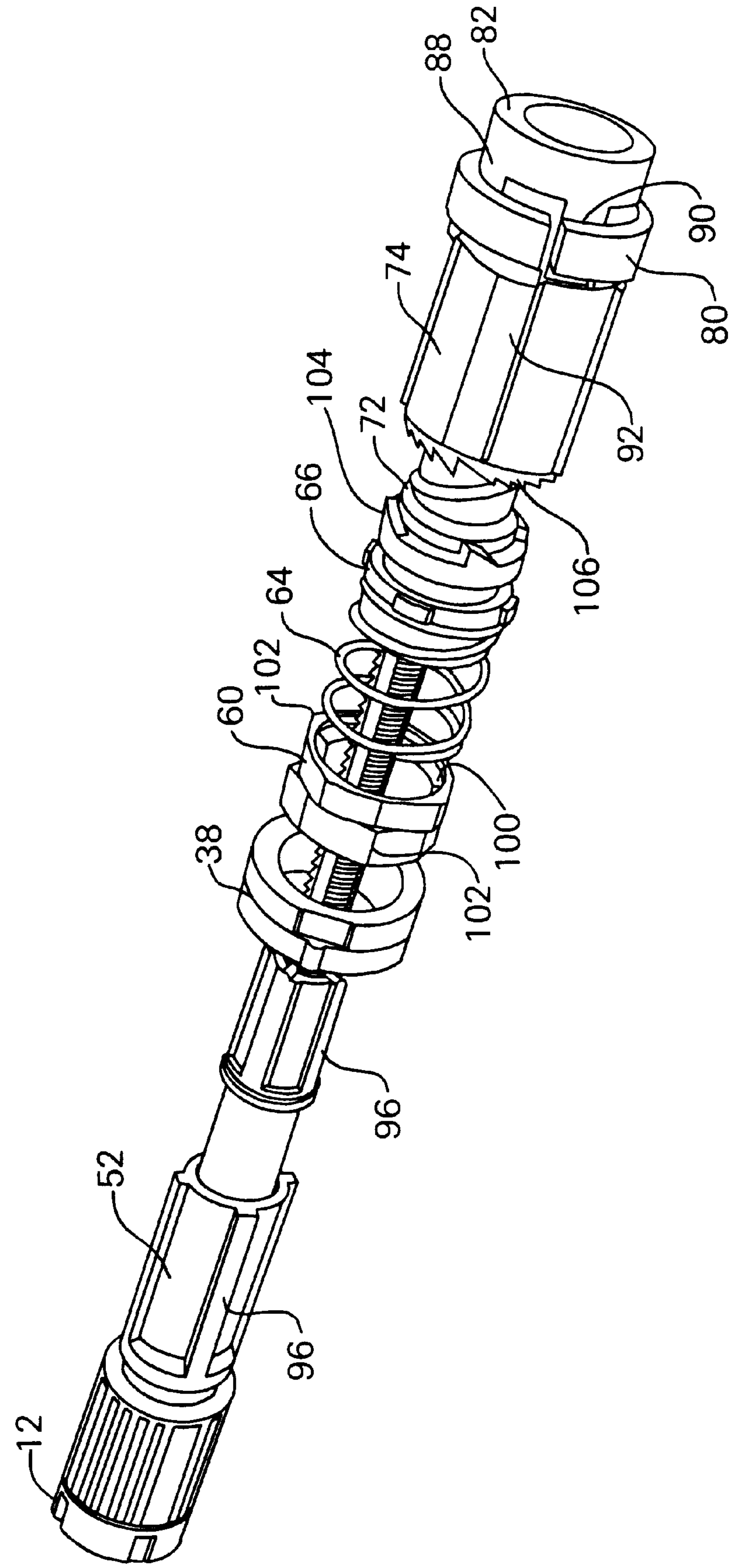

FIG. 12

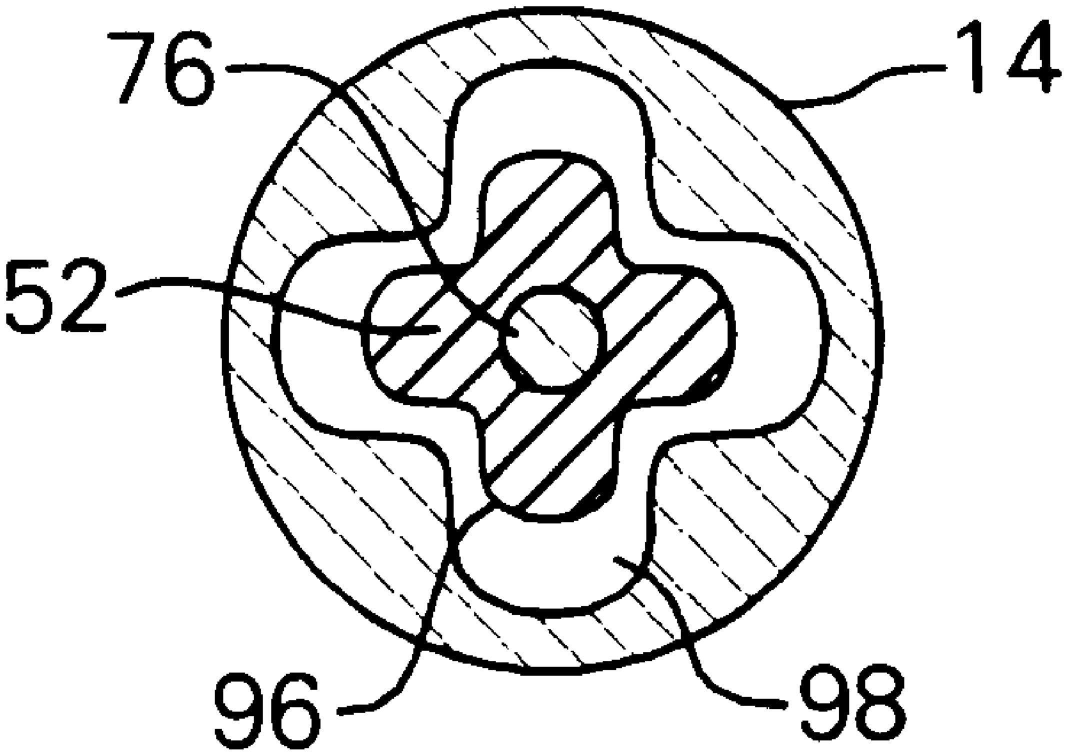

FIG. 13

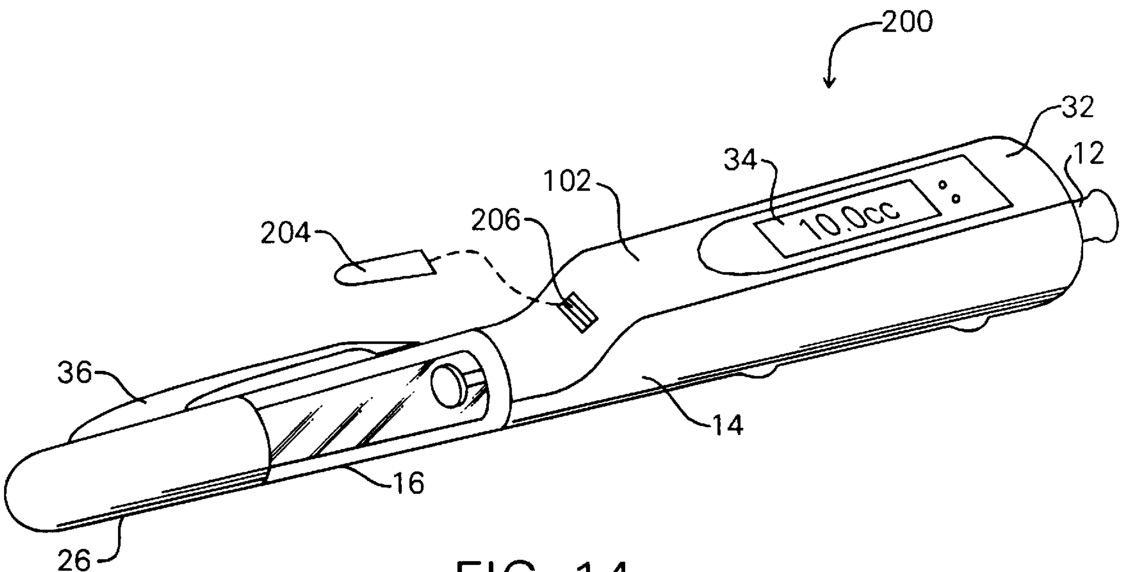
200
32
12
34
10.0cc
102
206
204
36
14
16
26

FIG. 14

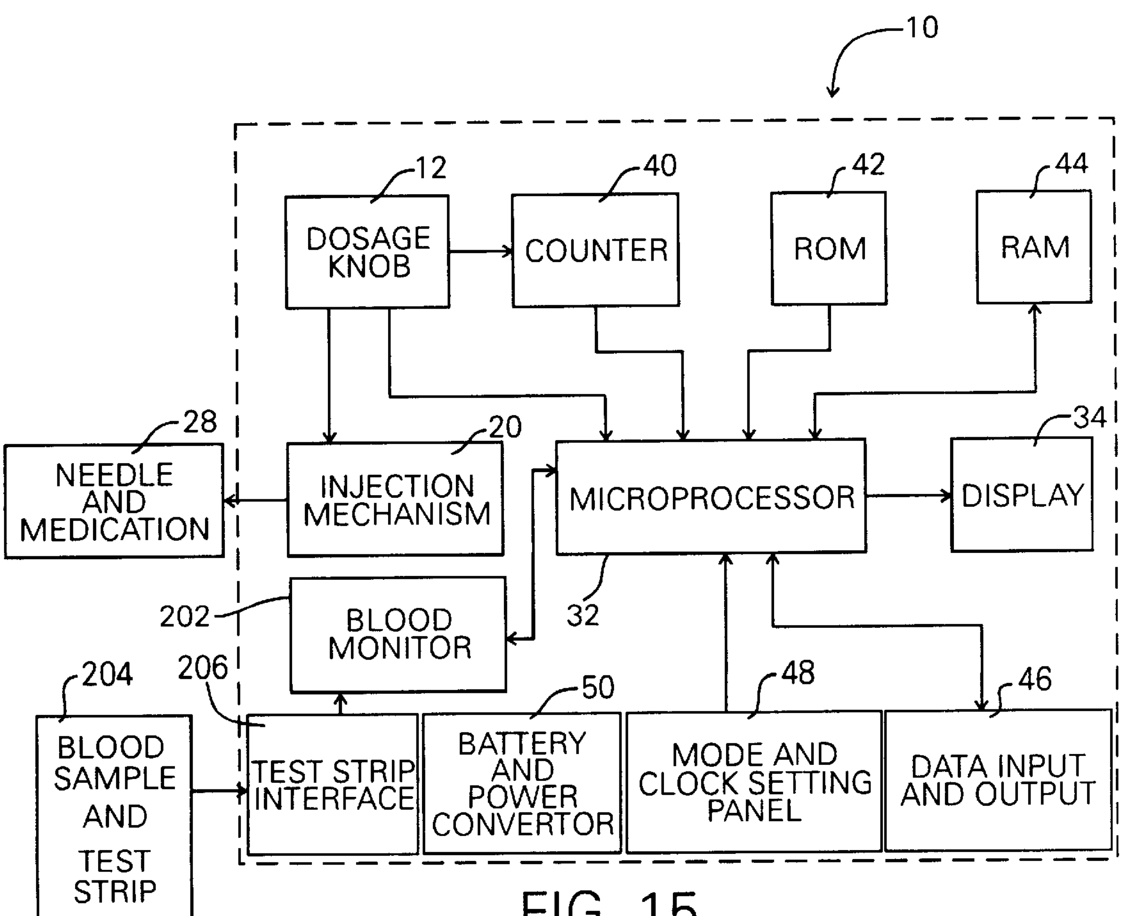
10
12
DOSAGE KNOB
40
COUNTER
42
ROM
44
RAM
28
NEEDLE AND MEDICATION
20
INJECTION MECHANISM
MICROPROCESSOR
34
DISPLAY
202
BLOOD MONITOR
32
204
BLOOD SAMPLE AND TEST STRIP
206
TEST STRIP INTERFACE
50
BATTERY AND POWER CONVERTOR
48
MODE AND CLOCK SETTING PANEL
46
DATA INPUT AND OUTPUT

FIG. 15

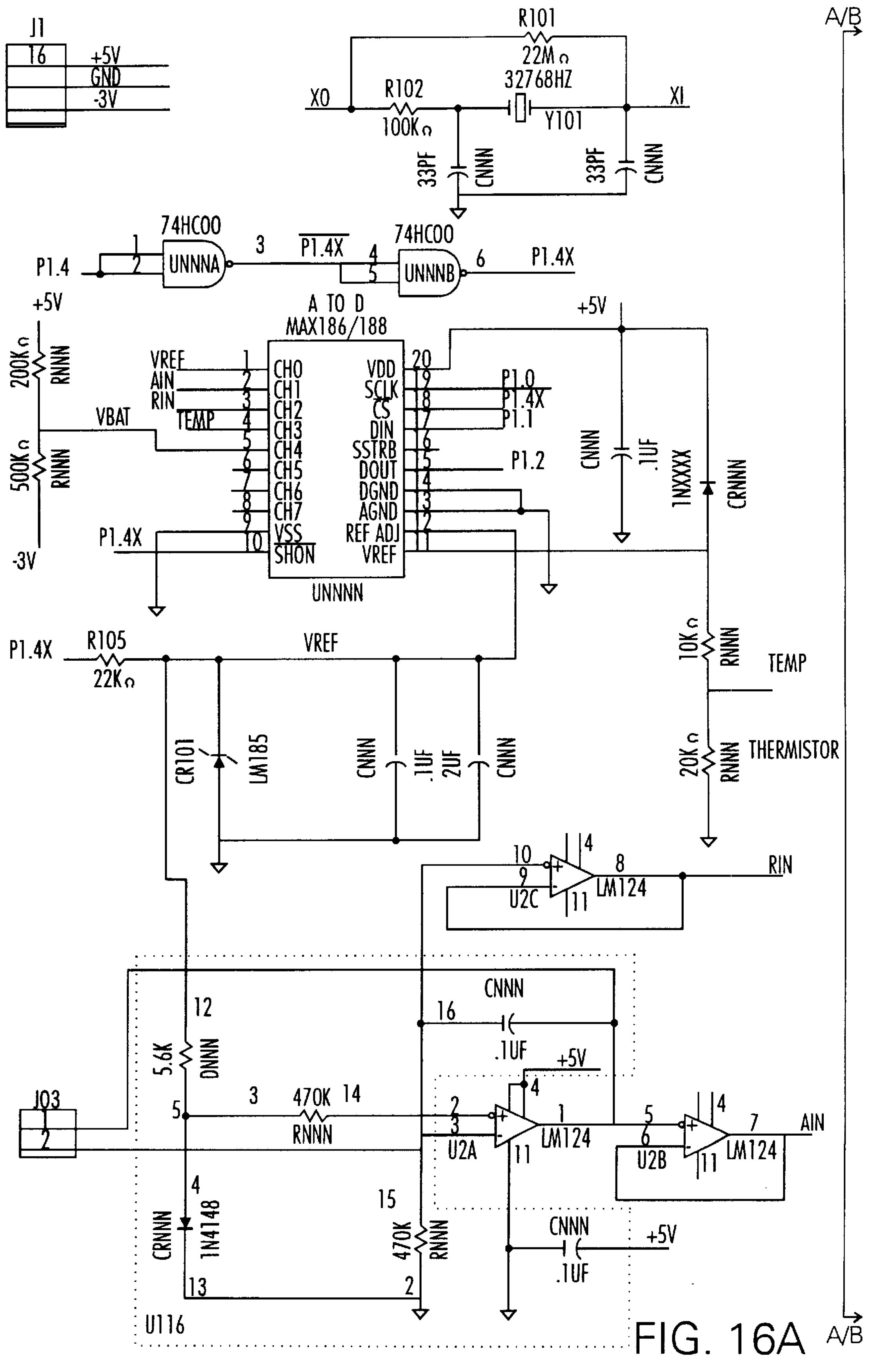
J1
16
+5V
GND
-3V
R101
22M
32768HZ
X0
R102
100K
Y101
XI
33PF
CNNN
33PF
CNNN
A/B
74HC00
UNNNA
P1.4
P1.4X
74HC00
UNNNB
P1.4X
+5V
200K
RNNN
500K
RNNN
VBAT
-3V
A TO D
MAX186/188
VREF
AIN
RIN
TEMP
CH0
CH1
CH2
CH3
CH4
CH5
CH6
CH7
VSS
SHDN
VDD
SCLK
CS
DIN
SSTRB
DOUT
DGND
AGND
REF ADJ
VREF
P1.0
P1.4X
P1.1
P1.2
P1.4X
UNNNN
+5V
CNNN
.1UF
1NXXXX
CRNNN
P1.4X
R105
22K
VREF
CR101
LM185
CNNN
.1UF
2UF
CNNN
10K
RNNN
TEMP
20K
RNNN
THERMISTOR
U2C
LM124
RIN
CNNN
.1UF
+5V
J03
5.6K
DNNN
470K
RNNN
U2A
LM124
U2B
LM124
AIN
CRNNN
1N4148
470K
RNNN
CNNN
.1UF
+5V
U116
A/B

FIG. 16A

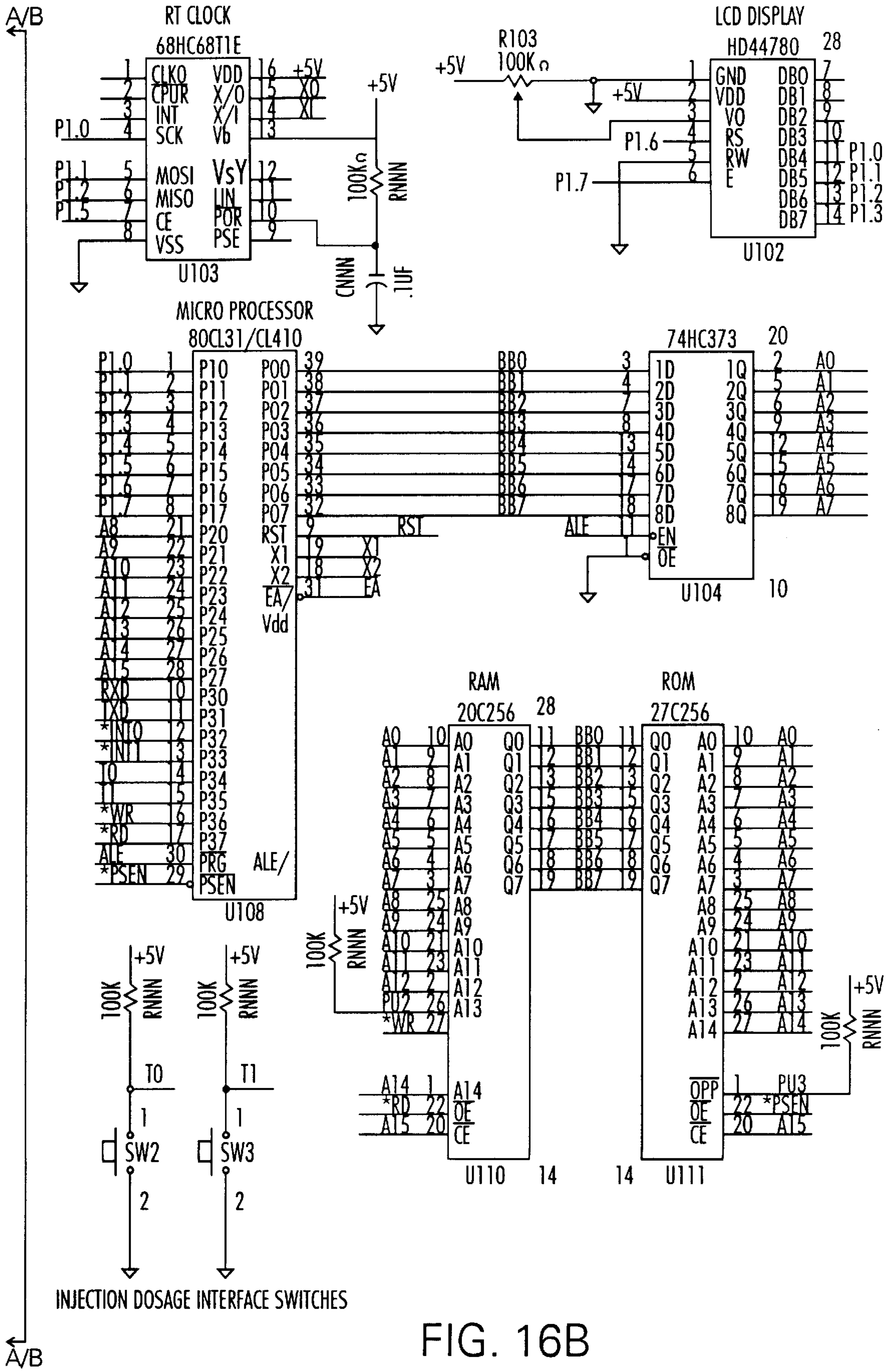
A/B
RT CLOCK
68HC68T1E
U103
LCD DISPLAY
HD44780
U102
R103
100K
MICRO PROCESSOR
80CL31/CL410
U108
74HC373
U104
RAM
20C256
U110
ROM
27C256
U111
SW2
SW3
INJECTION DOSAGE INTERFACE SWITCHES
A/B

FIG. 16B

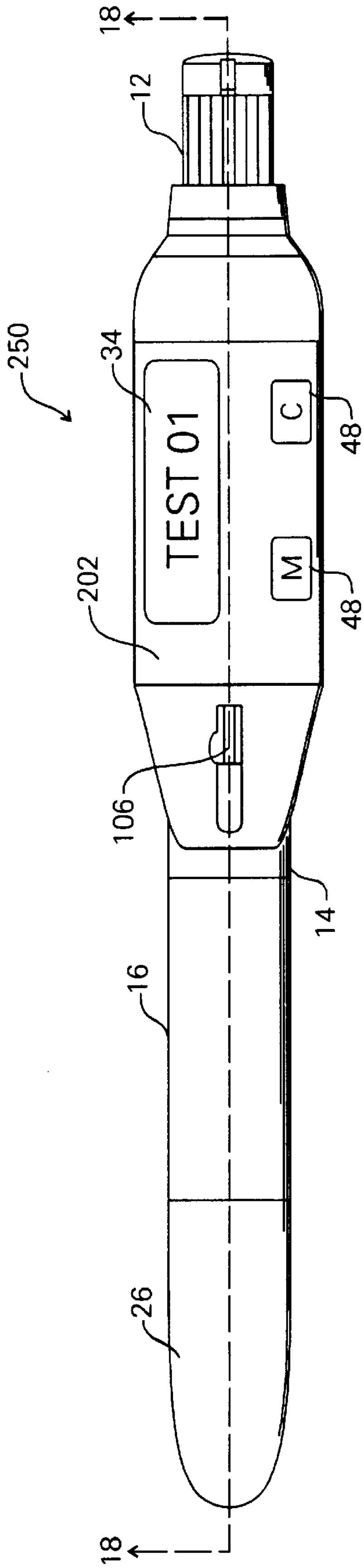
18
12
250
34
TEST 01
C
48
M
48
202
106
14
16
26
18

FIG. 17

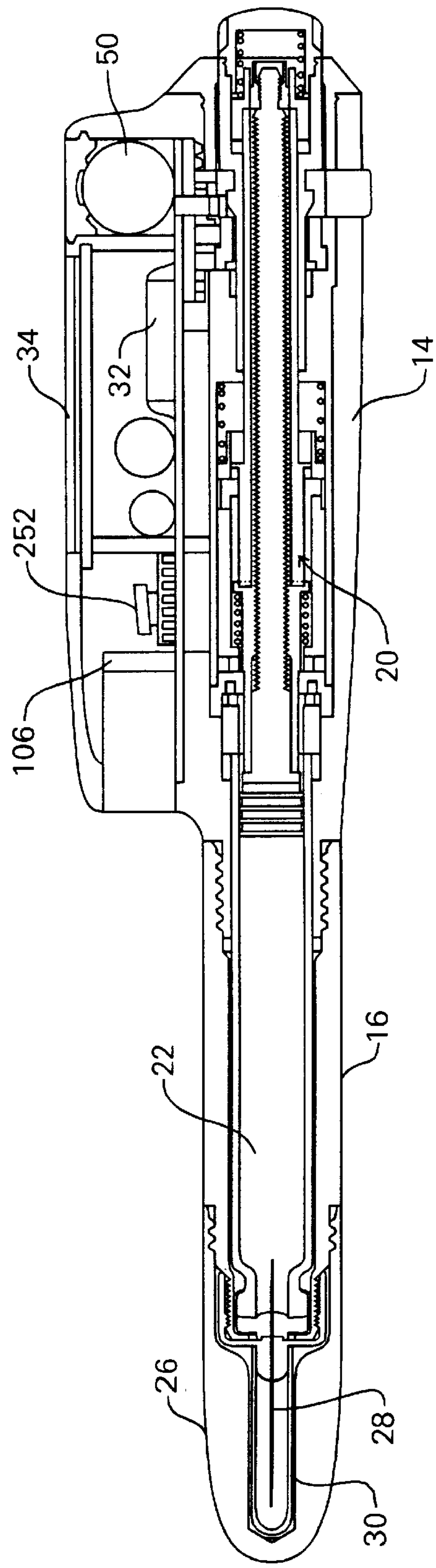
50
34
32
14
252
20
106
22
16
26
28
30

FIG. 18

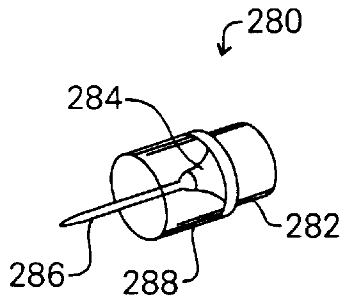

FIG. 19

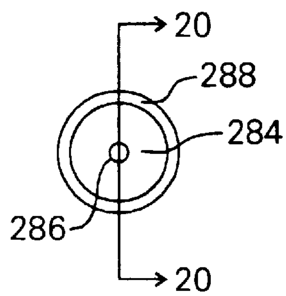

FIG. 20

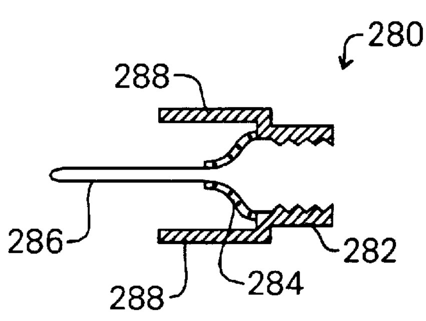

FIG. 21

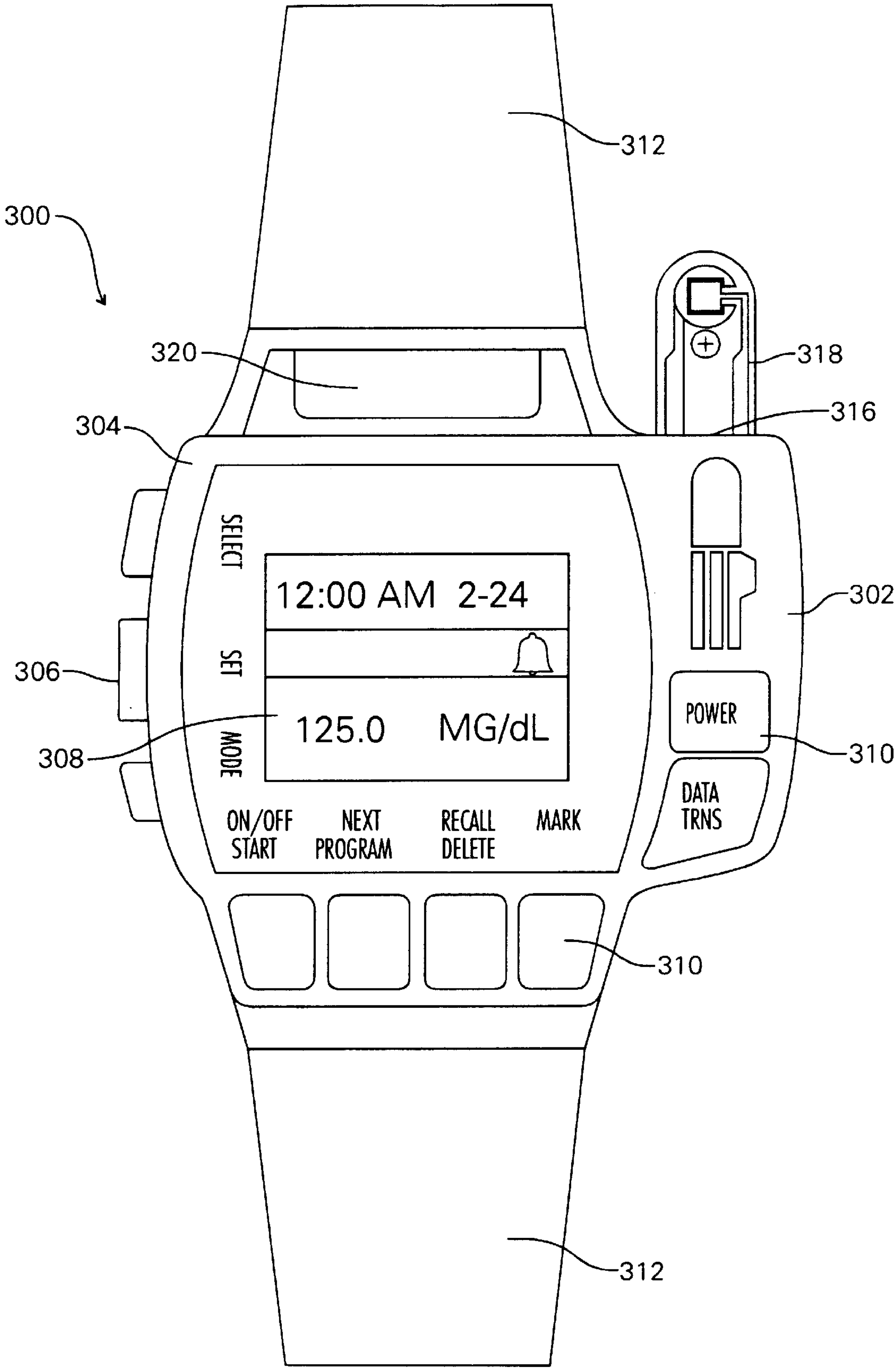
312
300
320
318
304
316
SELECT
12:00 AM 2-24
302
SET
306
125.0 MG/dL
POWER
308
MODE
310
DATA
TRNS
ON/OFF
START
NEXT
PROGRAM
RECALL
DELETE
MARK
310
312

FIG. 22

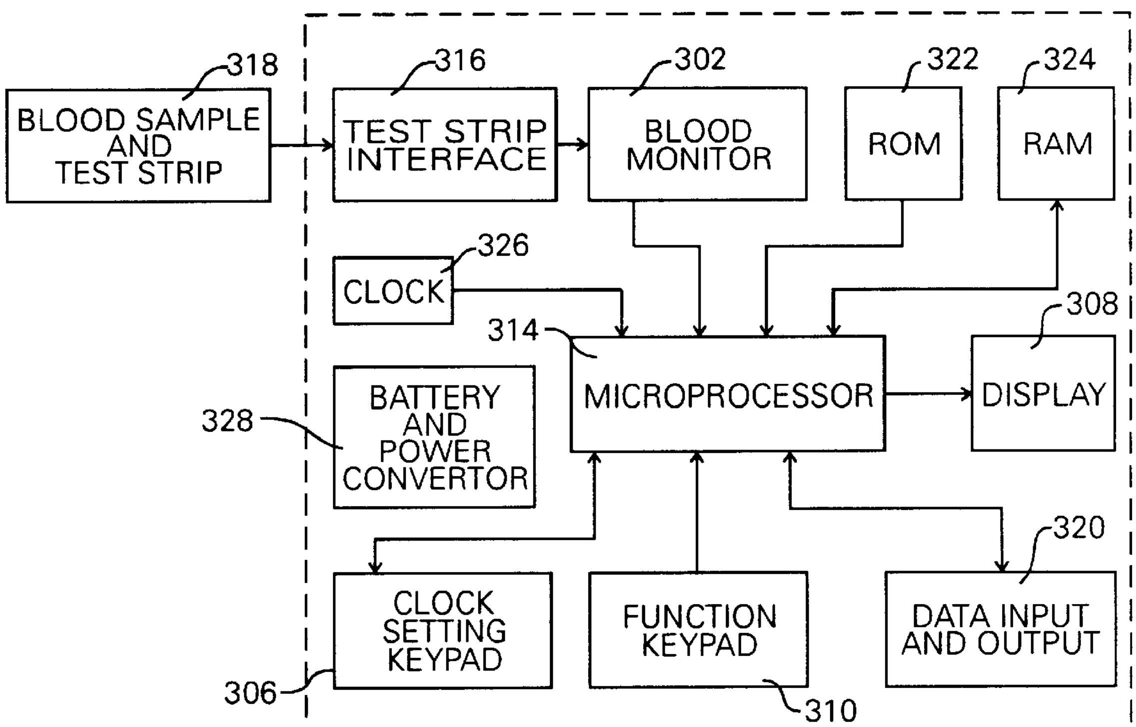
318
BLOOD SAMPLE AND TEST STRIP
316
TEST STRIP INTERFACE
302
BLOOD MONITOR
322
ROM
324
RAM
326
CLOCK
314
MICROPROCESSOR
308
DISPLAY
328
BATTERY AND POWER CONVERTOR
320
CLOCK SETTING KEYPAD
FUNCTION KEYPAD
DATA INPUT AND OUTPUT
306
310

FIG. 23

BLOOD GLUCOSE (mg/dL) INSULIN LOG

Name: Good, Johnny B. Report Date: 12-31-93
I.D. or Chart # Report Time: 13:50
Phys/Inst: Cedars S. Report Span: 12-24 to 12-30-93

	Breakfast		Lunch		Dinner		Snack
	Pre	Post	Pre	Post	Pre	Post	
No. of Readings	7	0	7	0	7	0	7
Std. Deviation	51.0		42.0		61.0		29.0
Average	99.3		113.4		130.4		86.0

FIG. 24(a)

Blood Glucose Chart:

	BLOOD GLUCOSE							
	Breakfast		Lunch		Dinner		Snack	Other
	Pre	Post	Pre		Pre	Post		
12-24-93 Fri	06:30 190		11:24 101		16:41 122		21:25 77	
12-25-93 Sat	06:41 47		11:20 146		16:20 137		21:15 123	
12-26-93 Sun	06:30 59		11:25 113		16:36 156		21:30 111	

FIG. 24 (b)

Insulin Chart:

	INSULIN			
	Breakfast	Lunch	Dinner	Evening
12-24-93 Fri	06:39 R-3 L-7	11:38 R-6 L-6	16:56 R-13 L-11	21:37 R-7 L-12
12-25-93 Sat	06:42 R-2 L-5	11:24 R-3 L-6	16:30 R-10 L-10	21:33 R-6 L-10
12-26-93 Sun	06:36 R-4 L-6	11:30 R-6 L-6	16:40 R-8 L-12	21:40 R-8 L-10

FIG. 24 (c)

Markers Chart:

	MARKERS			
	Symptom	Meal	Exercise	Special
12-24-93 Fri		17:15 inc		
12-25-93 Sat	06:00		18:30	
12-26-93 Sun			18:15 inc	

FIG. 24 (d)

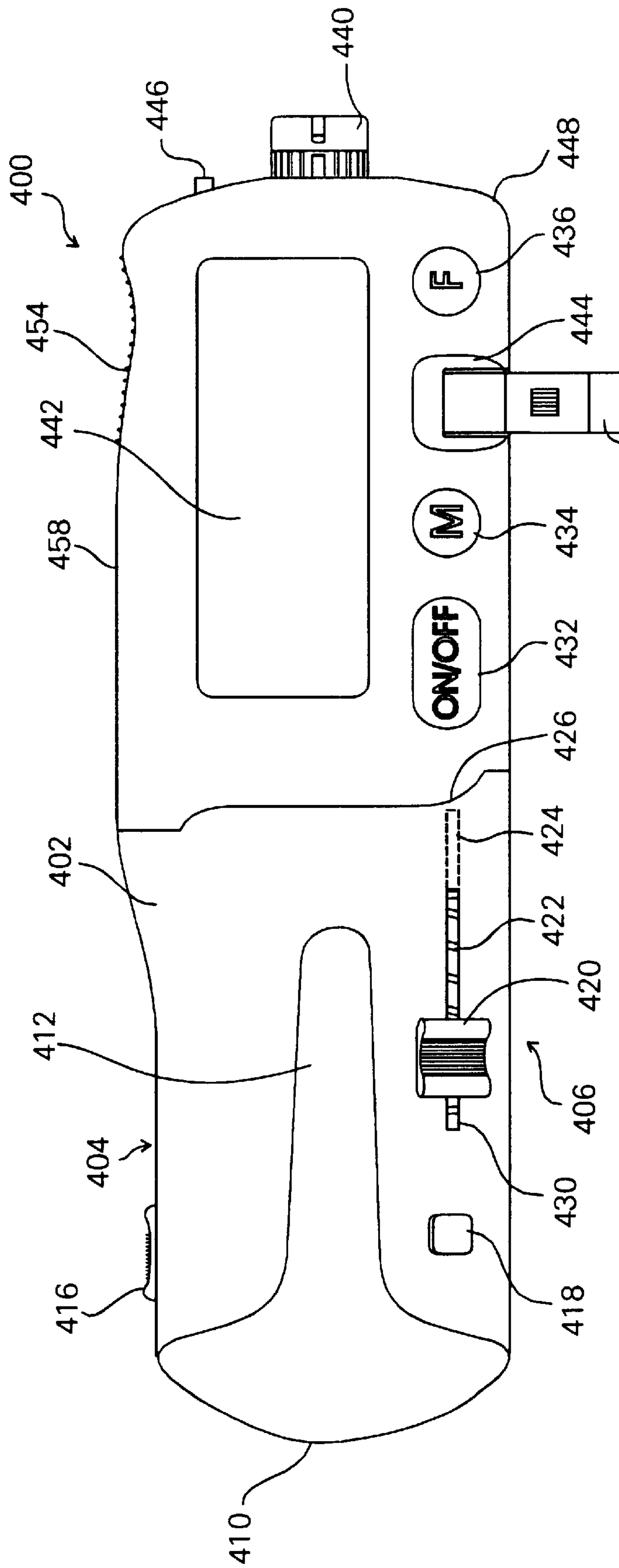
400
440
446
448
436
F
454
444
442
406
M
434
458
ON/OFF
432
426
424
402
422
420
412
406
404
430
416
418
410

FIG. 25(a)

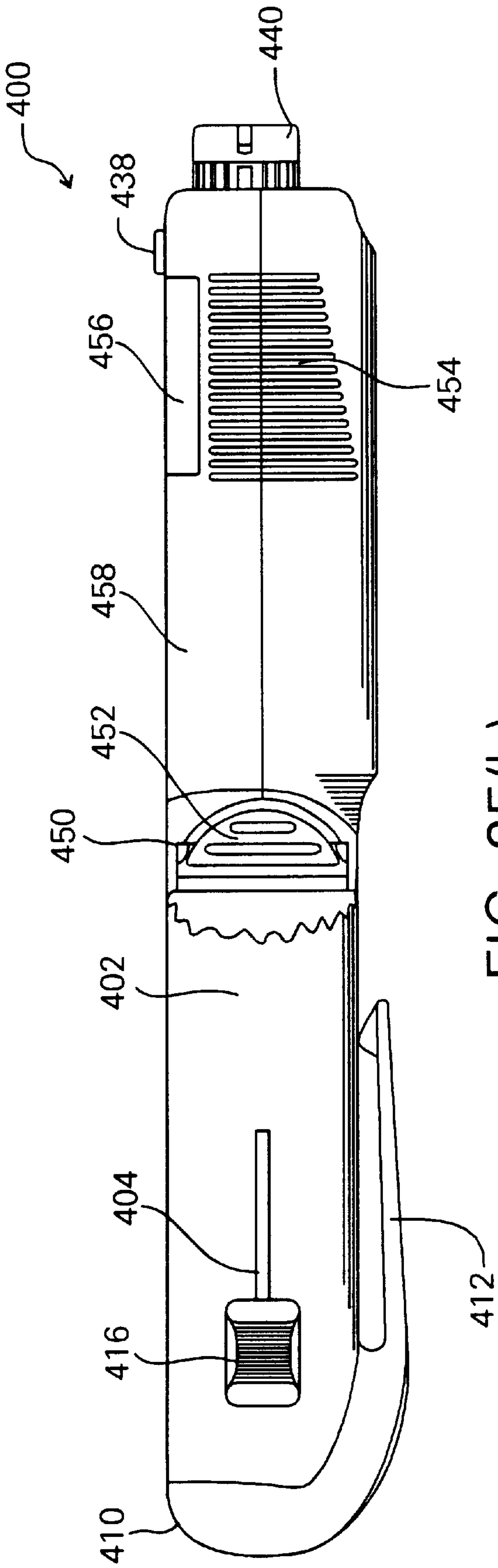

FIG. 25(b)

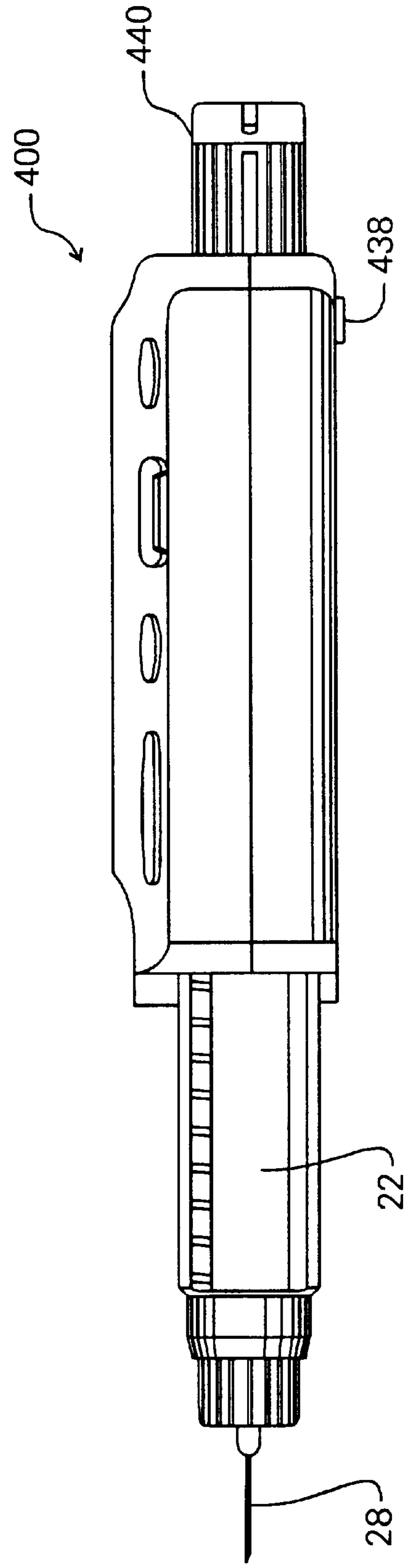

FIG. 25(c)

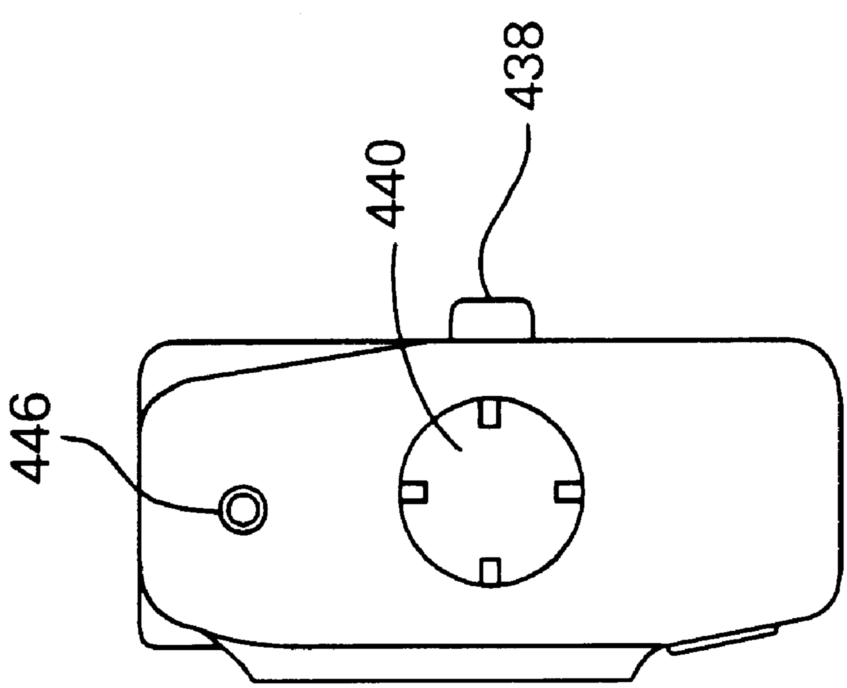

FIG. 25(d)

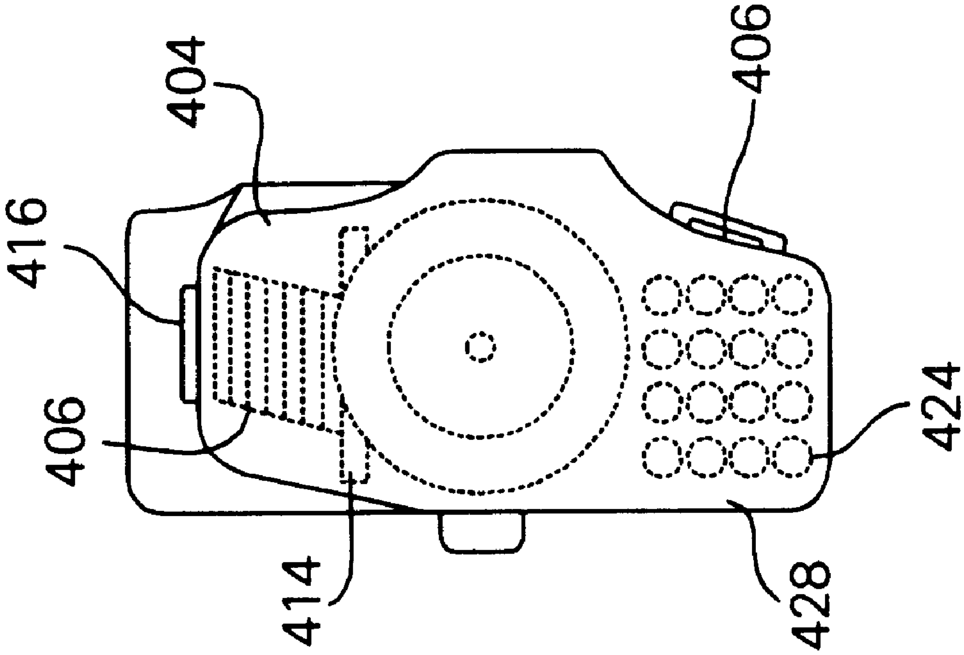

FIG. 25(e)

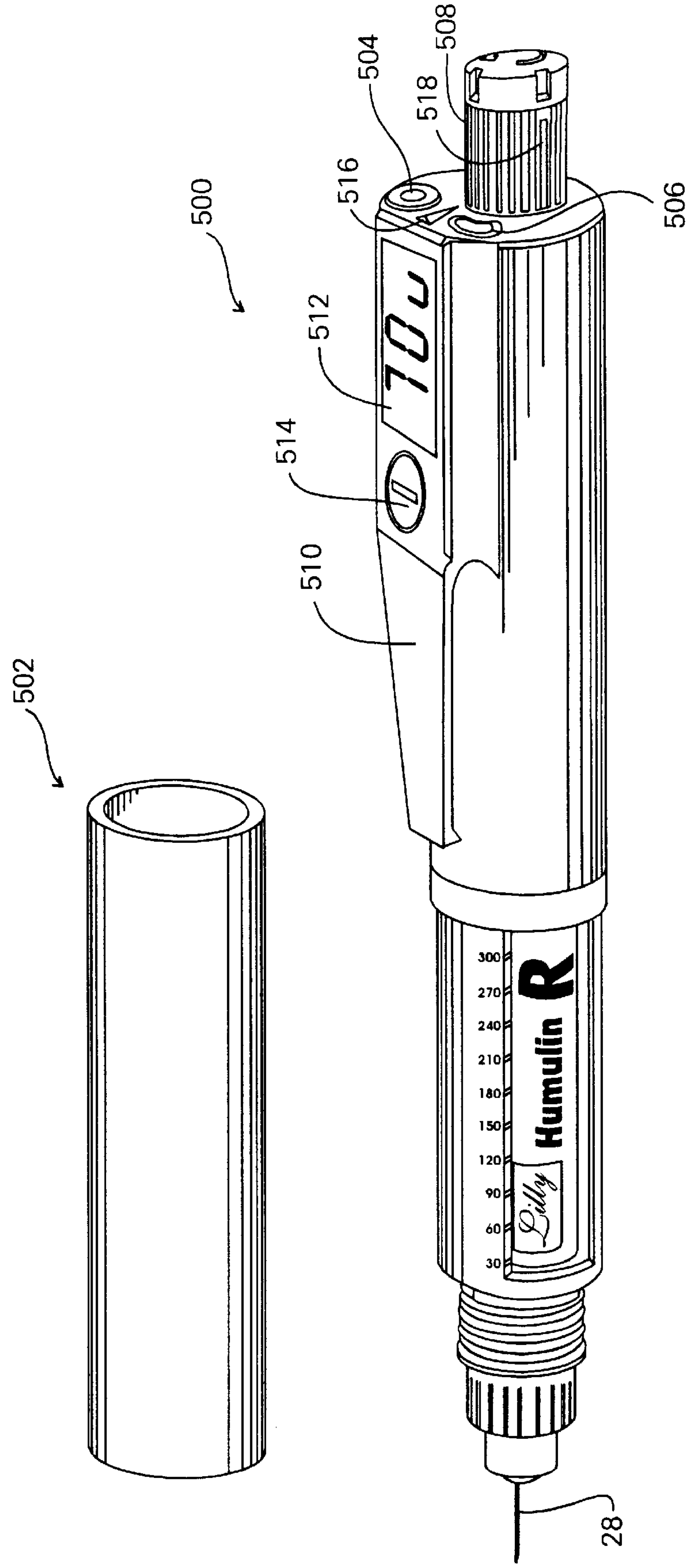
500
502
504
506
508
510
512
514
516
518
28
70u
300
270
240
210
180
150
120
90
60
30
Humulin R
Lilly

Fig. 26(a)

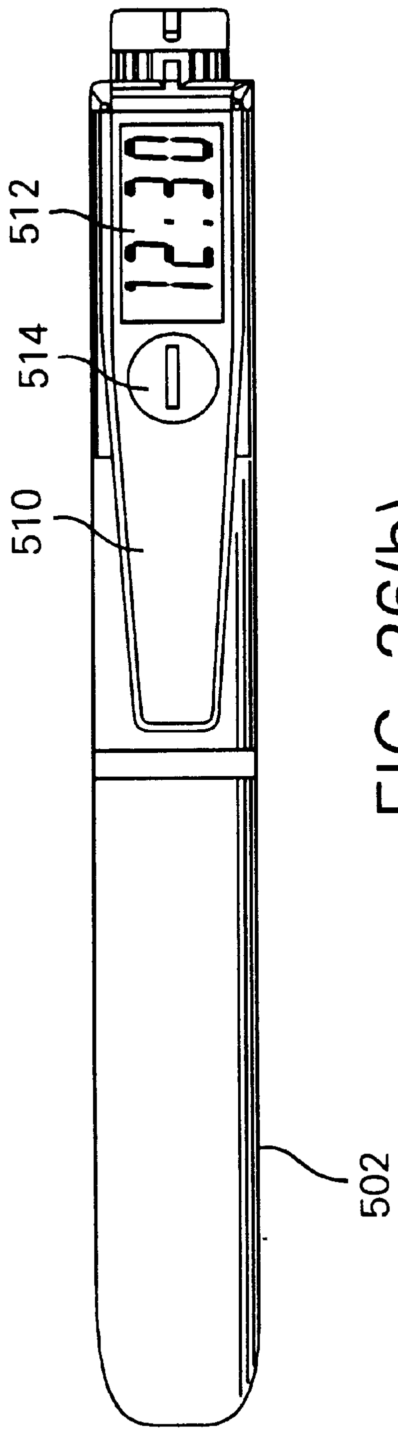

FIG. 26(b)

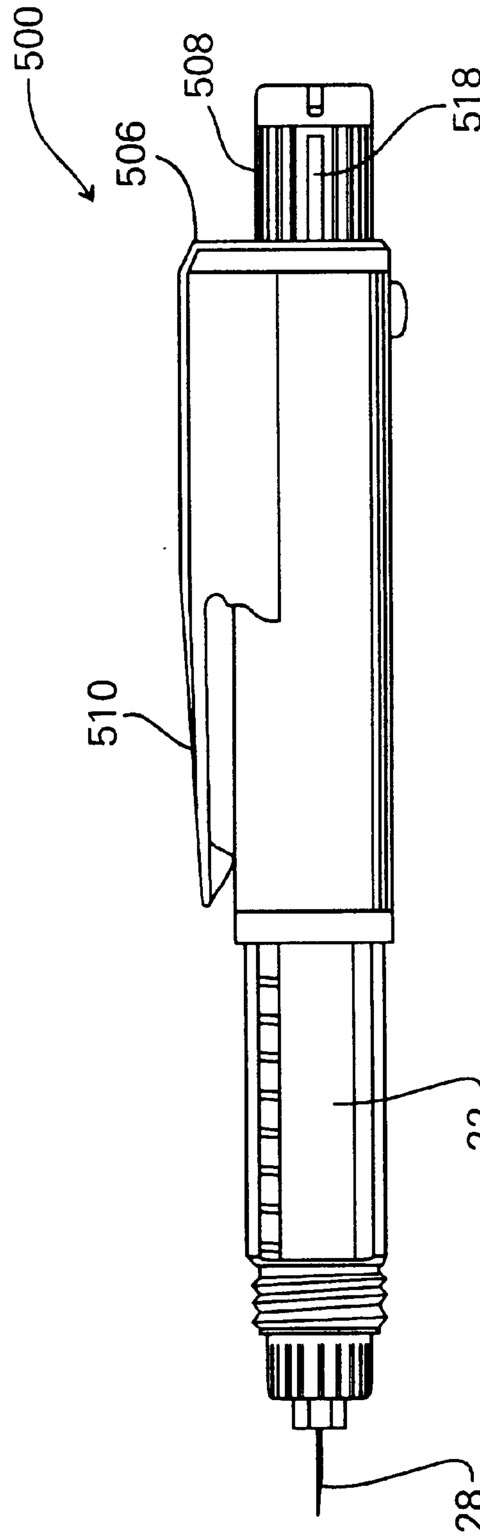

FIG. 26(c)

MEDICATION DELIVERY DEVICE WITH A MICROPROCESSOR AND CHARACTERISTIC MONITOR

This is a continuation of application Ser. No. 08/782,541 filed Jan. 10, 1997, now pending, a divisional of U.S. patent application Ser. No. 08/396,420 filed Feb. 28, 1995, now U.S. Pat. No. 5,593,390, which is a continuation-in-part of U.S. patent application Ser. No. 08/350,405 filed Dec. 5, 1994, now U.S. Pat. No. 5,728,074, which is a continuation-in-part of U.S. patent application Ser. No. 08/208,636 filed Mar. 9, 1994, now U.S. Pat. No. 5,536,249.

FIELD OF THE INVENTION

This invention relates to pen-type injectors for injecting medications or other injectable substances and, in particular embodiments, a pen-type injector for injecting insulin. In preferred embodiments, the pen-type injector utilizes a microprocessor to record injection information and a monitor to measure blood characteristics. Further embodiments of the invention also relate to other types of medication delivery devices that can utilize a microprocessor and a characteristic monitor.

BACKGROUND OF THE INVENTION

Home treatment methods for the control and management of various diseases are becoming more popular. For instance, high success rates for treatment of diabetes have been achieved when a diabetic patient controls the disease by self-testing blood glucose levels and administering a correct dose of insulin. The doctor works with the patient to determine the best regimen of diet, exercise, and insulin dose to maintain a target blood glucose level.

Between doctor's office visits, the patient is responsible for carrying out the prescribed regimen, which includes frequent blood testing and insulin administration using a syringe, needleless injector, pen-type injector or insulin pump. The patient and doctor select a blood glucose monitor based on desired monitor features, suitability for the patient, perceived accuracy, and ease of use.

Home diabetes therapy requires personal discipline of the user, is time consuming, requires an appropriate location, and the proper instruments and accessories. Therefore, it is highly desirable that the home therapy regimen cause minimal inconvenience and changes in the patient's lifestyle. Many past therapy regimens and devices have failed to provide the convenience and minimum changes to the patient's lifestyle, and thus the compliance with the medical regimens have been less than satisfactory.

Traditionally, for out-patient and in-home patient care, medication has been injected by a syringe, wherein the user has to insert the needle of the syringe into a separate medication vial to withdraw medication. Once the medication is withdrawn from the vial, the user removes any air bubbles and extra medication, and then injects the medication.

Typical syringes suffer from many drawbacks. For instance, they may not be preloaded with medication; thus, requiring the user to carry a separate medication vial. Moreover, people with dexterity disorders often have difficulty lining up the needle portion of the syringe with the rubber septum on the medication vial. This can lead to unintentional needle pricks or excessive time being required to complete an injection, both of which tend to inhibit compliance with a medical regimen. Also, it is often difficult for children or people with failing eyesight to line up the medication with the proper dosage line on the outer casing of the syringe. Furthermore, the user of the syringe is typically responsible for manually recording the date, the time and the dosage in a separate log book so that the doctor can monitor the user's compliance with the prescribed medical regimen.

Another drawback to the traditional syringe is that a syringe is difficult to use in public places. For instance, many schools do not allow students to carry syringes. This prohibition against syringes can cause excessive delays between injections, and thus could complicate a user's medical condition. Moreover, there is also a social stigma attached to using a syringe, since it raises connotations of drug abuse. These drawbacks have been one of the principal reasons why users have abandoned medical regimens requiring the use of syringes in social settings.

As an alternative, pen-type injectors have been developed. The pen-type injectors often use prepackaged insulin. However, these devices have been inherently inaccurate and undependable due to their difficult to read scales and inadequately designed mechanical injection systems. For example, typical pen-injectors require multiple and repeated activations of the injector mechanism to administer a desired dosage. Thus, during administration of an injection, the user must keep track of the number of activations (i.e., depressions) to determine when the required dosage has been delivered.

Another disadvantage to pen-type injectors is that typical disposable needles used on pen-type injectors cause bleeding during the administration of an injection. This results from the disposable needle spreading the opening in the skin at the injection site, thereby allowing the skin to bleed. This bleeding from traditional disposable needles can discourage users from following the medical regimen, and the bleeding also increases the likelihood of spreading infectious diseases.

Often a user who takes certain medications, such as insulin, in a home therapy regimen must also monitor the level of glucose present in the blood at periodic intervals. The test results are used to determine when another injection should be administered or to determine how the user is responding to prior injections. Typically, the blood monitor is a separate device that the user must carry along with the insulin injector or syringe. To use the blood monitor the user must lance a portion of the body (i.e., typically a finger) and take a sample that is analyzed by the monitor. The user then manually records the results, the time and the date in a separate log book.

SUMMARY OF THE DISCLOSURE

According to embodiments of the present invention, a medication delivery device, such as a pen-type injector, medication pump, inhaler, spray or the like, has a processor coupled to the medication delivery device that records the date, the time, and the amount of each medication delivery. The processor may also be coupled to a display to indicate the amount of medication to be delivered.

In particular embodiments, a medication delivery device includes a delivery mechanism that has an actuator for setting the dosage and administering a dosage of a medication contained within the medication delivery device. The medication delivery device also has a processor coupled to the actuator of the delivery mechanism to determine a value equal to the dosage set by the actuator of the delivery mechanism, and a memory device coupled to the processor to store the value determined by the processor. In further

embodiments, the medication delivery device also has a receptacle capable of holding the medication and the delivery mechanism further includes a drive mechanism coupled between the actuator and the receptacle to deliver the set dosage of the medication. In other embodiments, the medication delivery device also includes a display device to display the value equal to the dosage determined by the processor and a clock circuit for determining the time. In preferred embodiments, the medication delivery device includes a data port for transferring information to and from the processor and memory device to an external device.

In particular embodiments of the present invention, a medical device includes a medication delivery device that is also coupled with a characteristic monitor to analyze characteristics of a sample. This provides a single, all-in-one device that performs a variety of functions, and requires only minimal space.

In particular embodiments, a medical device includes a medication delivery device for delivering a dosage of a medication, a blood characteristic monitor for analyzing a blood sample, and a processor coupled to the medication delivery device and the blood characteristic monitor. The processor determines a value equal to the dosage of the medication to be delivered by the medication delivery device. The processor also determines blood characteristics from a blood sample analyzed by the blood characteristic monitor.

In further embodiments, the medical device also includes a memory device coupled to the processor to store the value equal to the dosage and the blood characteristics determined by the processor. In preferred embodiments, the medical device includes a data port for transferring information to and from the processor and memory device to an external device and a clock circuit for tracking the time.

According to another embodiment of the invention, a pen-type injector utilizes a disposable needle that substantially eliminates or reduces bleeding from an opening in the skin at the injection site. Also in other embodiments, the pen-type injector uses a direct drive mechanism for injecting the medication with a single depression of an actuator knob. Moreover, the actuator knob is rotatable to adjust the amount of medication that is injected.

In particular embodiments, a disposable needle for a pen-type injector has a base adapted to be coupled to a pen-type injector, an injection needle having an injection end and a connecting end, and a hollow cylindrical cover having an open end and an opposite connecting end. Both the connecting end of the injection needle and the opposite connecting end of the hollow cylindrical cover are coupled to the base such that the injection needle is disposed in the center of the open end of the hollow cylindrical cover with the connecting end of the injection needle inside the hollow cylindrical cover below the open end of the hollow cylindrical cover. Moreover, the injection end of the injection needle extends beyond the open end of the hollow cylindrical cover.

According to a further embodiment of the present invention, a watch monitor includes a blood characteristic monitor and a clock that performs as a wrist watch. The watch monitor utilizes a high quality blood analysis device that can record detailed information on blood analysis results and injections. Moreover, the device can be worn easy and unobtrusively on a wrist so that typical time and alarm functions are combined with the blood characteristic monitor to coordinate the blood testing regimen and reduce the number of items a user must carry. Thus, a user has improved detailed record keeping, regimen alarms and reminders, blood characteristic analysis capabilities, and time keeping functions in a single, all-in-one device.

In particular embodiments of the present invention, a portable blood monitor includes a housing of suitable size and configuration to be worn on a wrist, a clock contained in the housing for measuring time, and a blood characteristic monitor contained in the housing for analyzing a blood sample. The portable blood monitor also includes a processor coupled to the blood characteristic monitor and the clock. The processor determines blood characteristics based on the analyzed blood sample from the blood characteristic monitor, and the processor uses the measure of the time from the clock to identify when the blood characteristics were determined. In further embodiments, the portable blood monitor also includes a memory storage device coupled to the processor for storing the measure of time from the clock and the blood characteristics determined by the processor, and a display device to display the measure of the time from the clock and the blood level characteristics determined by the processor. In preferred embodiments, the portable blood monitor includes a data port for transferring information to and from the processor and memory device to an external device and the data port may utilize infrared communication technology to transfer the information.

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, various features of embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description of embodiments of the invention will be made with reference to the accompanying drawings, wherein like numerals designate corresponding parts in the several figures.

FIG. **1** is a perspective view of a pen-type injector in accordance with an embodiment of the present invention.

FIG. **2** is a front perspective view of the embodiment of the pen-type injector shown in FIG. **1**.

FIG. **3** is a partial cross-sectional and exploded side view of the pen-type injector shown in FIG. **2**.

FIG. **4** is a simplified flow block diagram for the pen-type injector as shown in FIG. **1**.

FIG. **5** is a cross-sectional view of the pen-type injector embodiment as shown along the line **5—5** in FIG. **2**.

FIG. **6** is another cross-sectional view of the pen-type injector shown in FIG. **5**, with the actuator in the released position.

FIGS. **7**(*a*)–**7**(*i*) show exploded views and details of a drive mechanism in accordance with an embodiment of the present invention. FIG. **7**(*a*) is an exploded view of the drive mechanism. FIGS. **7**(*b*) and **7**(*b*) are an alternative embodiment for a portions of the drive mechanism. FIG. **7**(*d*) is a further exploded view of an actuator knob drive shaft shown in FIG. **7**(*a*). FIGS. **7**(*e*)–**7**(*f*) show various views of a keyway bore in the actuator knob drive shaft shown in FIG. **7**(*a*). FIGS. **7**(*g*)–**7**(*i*) show various views of the threaded drive shaft shown in FIG. **7**(*a*).

FIGS. **8–12** show various views of the drive mechanism in accordance with an embodiment of the present invention.

FIG. **13** is a cross-sectional view of the pen-type injector as shown along the line **13—13** in FIG. **6**.

FIG. **14** is a perspective view of a pen-type injector that includes a blood characteristic monitor in accordance with an embodiment of the present invention.

FIG. **15** is a simplified flow block diagram for the pen-type injector with a blood characteristic monitor as shown in FIG. **14**.

FIGS. **16**A–**16**B are a circuit schematics for the pen-type injector with a blood characteristic monitor shown in FIGS. **14** and **15**.

FIG. **17** shows a top view of another pen-type injector with a blood characteristic monitor in accordance with an embodiment of the present invention.

FIG. **18** is a cross-sectional view of the pen-type injector with a blood characteristic monitor as shown along the line **18**—**18** in FIG. **17**.

FIG. **19** is a perspective view of a disposable needle in accordance with an embodiment of the present invention.

FIG. **20** is an end view of the disposable needle as shown in FIG. **19**.

FIG. **21** is a cross-sectional view of the disposable needle as shown along the line **21**—**21** in FIG. **20**.

FIG. **22** is a front plan view of a blood characteristic monitor in accordance with an embodiment of the present invention.

FIG. **23** is a simplified flow block diagram in accordance with the embodiment shown in FIG. **22**.

FIGS. **24**(*a*)–**24**(*d*) are diagrams of typical reports obtained from the embodiment shown in FIGS. **22** and **23** or other embodiments.

FIGS. **25**(*a*)–**25**(*e*) are views of a pen-type injector with a blood characteristic monitor in accordance with an embodiment of the present invention.

FIGS. **26**(*a*)–**26**(*c*) are views of a pen-type injector in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the invention is embodied in a medication delivery device utilizing a microprocessor. In particular embodiments of the present invention, the medication delivery device further includes a characteristic monitor to measure characteristics of a sample from a patient. In further embodiments, the medication delivery device uses a direct drive injection mechanism, and may include a disposable needle which substantially eliminates or reduces bleeding caused from administration of an injection. In other embodiments, a blood characteristic monitor is contained within a wrist watch sized device that combines blood characteristic monitoring, time keeping and information recording in a single, all-in-one device that is worn on a user's wrist.

In preferred embodiments of the present invention, the medication delivery device is used to deliver insulin, and the characteristic monitor is used to determine the amount of glucose present in a blood sample. However, it will be recognized that further embodiments of the invention may be used with other types of medication or other injectable or deliverable substances, such as vitamins, growth hormones or the like. Moreover, embodiments of the present invention may be used with various types of medication delivery devices such as pen-type injectors, jet injectors, medication pumps, inhalers, sprays and the like. Furthermore, in other embodiments, the blood characteristic monitor may be used to monitor other characteristics, such as hormone levels, cholesterol levels or the like. In alternative embodiments, a different type of characteristic monitor may be used, such as for determining the characteristics of a urine sample, a saliva sample or the like.

Embodiments of the present invention combine medication delivery devices, such pen-type injectors or the like, with a microprocessor to accurately set and determine the dosage of a medication that is administered to the user. Moreover, the microprocessor serves to record important information concerning the medication delivery, such as the date, the time and the amount of medication administered. This information is displayed on an LCD display, or the like, for easy review by the user or doctor. This allows the user to carry one self-contained medication delivery device that does not require carrying a separate medication vial and syringes, since, for example, the vial is contained within the pen-type injector or the like. Moreover, the user does not have to carry a separate log book to record relevant and required information concerning the injection, blood characteristics, meals, exercise, unscheduled events or the like, since this information is automatically recorded by the microprocessor for later recall.

Embodiments of the present invention are portable and compact, which is essential for a person with diabetes who is required to inject insulin multiple times a day. It is especially beneficial for children with diabetes who must take the device to school (where syringes are banned) and use it under the supervision of an adult who may not be a Registered Nurse. Embodiments of the device automatically record the insulin dosage type, amount, date and time in memory. This feature is especially beneficial to the supervising health care professional, patient and parent, since they now have accurate (unalterable) records of the patients daily treatment regimen for analysis. In addition to convenience, a medication delivery device with memory provides a substantial cost savings compared to syringes and bottled insulin. Particular embodiments also include programmable daily alarms with reminder messages and a clock to assist the user in maintaining a medical regimen.

A preferred embodiment of a pen-type injector has a direct drive injection mechanism for accurate dosing and ease of use. The drive utilizes a rotatable dosage knob provided at one end of the pen-type injector. The dosage knob allows the user to accurately adjust the amount of medication or insulin that will be injected by the pen-type injector, since rotating the dosage knob limits the distance that the dosage knob can be depressed. Accuracies of 0.001 to 0.01 ccs (0.1 to 1.0 units) can be readily achieved. To inject a dose of medication, the user inserts the needle under the skin and depresses the dosage knob once as far as it will depress.

In preferred embodiments, the medication delivery device is also combined with a blood characteristic monitor that determines the level of medication, glucose or the like in a blood sample. The blood characteristic monitor uses the microprocessor in the medication delivery device (although a separate microprocessor could be used) to process the blood sample results and to store relevant information about the results. Thus, a single, all-in-one device provides medication delivery, blood characteristic monitoring, and record keeping. Therefore, a user is only required to carry a single device, and is not required to carry a large number and variety of items to comply with their medical regimen. For example, a separate medication vial, a separate medication injector, a separate blood characteristic monitor and a separate log book are not needed.

In other embodiments, a pen-type injector utilizes a disposable needle that minimizes or substantially eliminates the bleeding that may occur from administering an injection. The disposable needle includes a protective, hollow cylindrical cover that prevents the user from pushing the needle

too deeply into the skin. Moreover, the hollow cylindrical cover tends to press the skin together during the administration of an injection to restrict and substantially eliminate bleeding during the injection.

In another preferred embodiment of the present invention, a portable blood monitor combines a blood characteristic monitor with a wrist watch. The blood characteristic monitor is coupled to a microprocessor to analyze blood samples and record relevant data for later recall. The wrist watch performs time keeping functions and provides alarms to notify the user when to monitor blood characteristics and when to administer injections. In particular embodiments, the portable blood monitor has a plurality of keys that allow the user to input additional information concerning injections and special events. In other embodiments, the portable blood monitor includes a data input and output port to provide the capability of programming the portable blood monitor through an external computer, such as a PC, laptop or the like, and to provide for the capability to download the stored information to an external computer for detailed review and analysis by the user or doctor.

FIGS. **1–3** show a pen-type injector **10** with a microprocessor **32** in accordance with an embodiment of the present invention. The pen-type injector **10** includes a rotatable actuator dosage knob **12**, an injection housing **14**, and a medication cartridge housing **16** having a view window **18**. The actuator knob **12** is coupled to one end of the injection housing **14**, and is also operatively coupled to an injection mechanism **20** (see FIG. **3**) that is contained within the injection housing **14**. The medication cartridge housing **16** is sized to hold a medication cartridge **22** (see FIG. **3**) and is coupled to the other end of the injection housing **14** so that the injection mechanism **20** is operatively coupled to the medication cartridge **22**. In preferred embodiments, the medication cartridge housing **16** is coupled to the injection mechanism housing **14** by threads, and the medication cartridge **22** is connected to the medication cartridge housing **16** by threads, a friction fit or the like. In particular embodiments, the medication cartridge **22** contains 1.5 ccs (150 units); however, medication cartridges containing more or less medication may be used. In preferred embodiments, the medication cartridge **22** is a Novolin® cartridge by Novo Nordisk Pharm, Inc., an insulin cartridge by Eli Lilly, Inc or any other ISO standardized cartridge.

The view window **18** of the medication cartridge housing **16** allows the user to view the interior contents of the medication cartridge **22**. Thus, a user can visually determine when a medication cartridge **22** needs to be replaced with a refill medication cartridge **22**, or the user can visually determine the type of medication that is currently contained in the medication cartridge housing **16**.

Coupled to the other end of the medication cartridge housing **16** is a needle base **24** for holding a protective needle cover **26** and a disposable needle **28**. The needle cover **26** and the disposable needle **28** are detachably coupled to the needle base **24** by threads, friction or the like. The protective needle cover **26** prevents needle pricks until an injection is to be administered. The use of a disposable needle **28** reduces the chances of spreading infections and allows the pen-type injector to be used multiple times. In preferred embodiments, the disposable needle **28** also includes a protective needle sheath **30** to further reduce the likelihood of unintended needle pricks. In particular embodiments, the pen-type injector uses a 27 gauge disposable needle **28**; however, other gauges may be used.

Also attached to the injection mechanism housing **14** is a microprocessor **32**, a display **34** and a clip **36**. The microprocessor **32** accurately determines the dosage of the medication to be injected based upon the rotations of the actuator knob **12** by the user. The microprocessor **32** provides the dosage information to the display **34** to inform the user of the amount of medication that will be injected. In particular embodiments, the display **34** may include a set of user actuatable buttons to set various parameters in the microprocessor, such as the time, the date or the like. This allows the user to utilize the pen-type injector **10** like a clock and to set reminder alarms. The clip **36** attached to the injection mechanism housing **14** provides the capability for the pen-type injector **10** to be carried around like a traditional ball point pen. For example, the pen-type injector **10** can be carried unobtrusively in a shirt pocket or on a clip board.

As shown in FIG. **3**, the injection mechanism housing **14** also includes a start button **38**. The start button **38** releases the actuator knob **12** from the position shown in FIGS. **1–2** to the released position shown in FIG. **3**. The start button **38** locks the actuator knob **12** in the depressed position to prevent accidental discharges of the medication until an injection is to be administered. The start button **38** also activates the microprocessor **32** only when the microprocessor **32** is needed, and this reduces the overall power consumption characteristics of the device.

In preferred embodiments, the actuator knob **12**, the injection housing **14**, the medication cartridge housing **16**, the needle base **24**, the protective needle cover **26**, and the start button **38** are formed from a plastic material. However, in alternative embodiments, some or all of these parts may be formed from metals, ceramics or other suitable materials. In preferred embodiments, the view window **18** is formed from plastic; however, glass may be used in alternative embodiments. In preferred embodiments, the display **34** is an LCD display; however, in other embodiments, the display may use fluorescent elements, LEDs, electro-luminescent LCDs or the like.

FIG. **4** illustrates a simplified flow block diagram of the pen-type injector **10** shown in FIGS. **1–3**. The actuator dosage knob **12** is rotated to adjust the injection mechanism **20** and set the dosage of the medication to be injected by the disposable needle **28**. In preferred embodiments, the actuator knob **12** can be rotated in two directions to both increase or decrease the dosage level. The actuator knob **12** is coupled to a counter **40** that keeps track of the incremental rotations of the actuator knob **12** and injection mechanism **20**. In particular embodiments, the counter **40** is an electronic counter, and in preferred embodiments the electronic counter is bi-directional and can increment and decrement the dosage level. The counter **40** is coupled to the microprocessor **32** to provide the current count in the counter **40** to the microprocessor **32**. The current count from the counter **40** is converted into a value equal to the dosage of the medication that will be administered by an injection. The actuator knob **12** is also coupled directly to the microprocessor **32** to activate the microprocessor **32**. Thus, when the start button **38** releases the actuator knob **12**, the microprocessor **32** is prepared to store relevant information concerning the injection. For instance, the microprocessor **32** will store, the time, the date and the amount of medication injected by the user.

The microprocessor **32** is coupled to a ROM **42** and a RAM **44**. In preferred embodiments, the ROM **42** is an EPROM and the RAM **44** is a static RAM; however, other comparable memory storage components such as dynamic RAM, non-static RAM, rewritable ROMs or the like may be used. The ROM **42** stores the programs used by the micro-

processor **32** to determine various parameters, such as the amount of medication to be injected based upon the count from the counter, the date and the time, and how to report information to the user. The RAM **44** is used by the microprocessor **32** to store information about the injection for later recall by the user or the doctor. For example, a user or doctor can transcribe the stored information at a later time to determine compliance with the medical regimen. This is accomplished by downloading the information to the display **34** and then transcribing all of the stored records at one time as they appear on the display **34**.

In preferred embodiments, the microprocessor **32** is coupled to a data input and output (I/O) port **46**, and the user can download the stored information to an external computer (not shown) through the data I/O port **46** to produce a report such as shown in FIG. **24**(*c*). The data I/O port **46** is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor. In preferred embodiments, the I/O port **46** uses infrared (IR) technology or bar code readers. However, in alternative embodiments, the I/O port **46** may use other data transfer technologies such as cables, fiber optics, radio waves or the like.

Also coupled to the microprocessor **32** is a mode and clock setting panel **48** that provides the user with the capability to store additional information, set the date and the time, or set alarms to indicate when to take the next injection. The panel **48** is used in conjunction with the display **34** to access the various modes and alarms utilizing methods typically employed to set the time on an LCD watch or the like.

The pen-type injector **10** also includes a self contained battery and power convertor **50**. The battery is a small watch type battery, or in preferred embodiments, the battery is a lithium battery capable of providing power for up to 5 years.

Operation of the embodiment shown in FIGS. **1–4** is relatively simple. The user prepares the pen-type injector **10** by depressing the start button **38** to activate the microprocessor **32**. If a new medication cartridge **22** is required, the user unscrews the medication cartridge housing **16** from the injection mechanism housing **14**, and couples a pre-filled medication cartridge **22** to the injection mechanism **20** and the injection mechanism housing **14**. Once the medication cartridge **22** is attached, the user rescrews the medication cartridge housing **16** onto the injection mechanism housing **14**. Next, the user removes the protective needle cover **26**, and attaches a disposable needle **28** to the needle base **24**. The user then holds the pen-type injector **10** with the disposable needle **28** pointing upward and rotates the actuator knob **12** to set a small amount of medication (typically 2–4 units). The user then depresses the actuator knob **12** to eliminate the small amount of medication and remove the air from the disposable needle **28**. The user may also use a recall and delete function to delete the air removing injection from memory to prevent it from being stored with the other stored data. Alternatively, the user can mark this entry as an air removal injection, once it is stored in the memory. Depression of the actuator knob **12** delivers the set amount of medication. The system then remains on for 60 seconds (although longer or shorter times may be used) after the actuator knob **12** has been depressed so that the user can delete the most recent entry such as an air shot. After 60 seconds (although longer or shorter times may be used), the pen-type injector powers itself down. Finally, the user reattaches the protective needle cover **26** to prevent inadvertent needle pricks or damage to the disposable needle **28**.

To give an injection with the pen-type injector **10**, the user removes the protective needle cover **26** and, if present, the protective needle sheath **30**. The actuator knob **12** is released and the microprocessor **32** is activated by depressing the start button **38**. In preferred embodiments, when activated, the microprocessor **32** displays the time and the amount of the last injection on the display **34** in an alternating sequence for 5 seconds (although longer or shorter periods may be used) to remind the user of the last injection event. This substantially reduces the chance of “double dosing” (i.e., taking too much medication). After the reminder display, the pen-type injector **10** automatically zeros itself so that the user can dial in and set the dosage by rotating the actuator knob **12** in one direction (typically clockwise) until the desired amount of the medication to be injected is displayed on the display **34**. In particular embodiments, the display **34** changes in real time, and in preferred embodiments, an audible click or beep is heard as the user rotates the actuator knob **12**. Also in preferred embodiments, each click represents an incremental change in the dosage selected (i.e., 0.1, 0.25, 0.5 or 1.0 units). In bi-directional models, the user can increase or decrease the amount of medication to be injected. However, the microprocessor **32** will not allow the user to set a dosage below zero or to select a dosage larger than the amount of medication remaining in the medication cartridge **22**. If any incorrect dosage is selected or any step in the injection process is not properly performed, an error message will be displayed on the display **34**.

In further embodiments, if an injection or other function is not performed within a predetermined period of time (e.g., 1 minute or the like), the pen-type injector shuts down to conserve power in a “sleep mode.” Activation of a function button or turning the dosage knob **12** will reactivate the pen-type injector **10**.

After the dosage is selected, the user chooses an injection site, pushes the disposable needle **28** under the skin and depresses the actuator knob **12** down as far as it will go. The actuator knob **12** automatically locks in the depressed position when the actuator is depressed completely and the injection is completed. When the actuator knob **12** is depressed, the microprocessor **32** stores the injection event in the RAM **44** by the date, the time and the amount of injected medication. When the user returns home or after a certain number of injections have been administered, the user can activate the microprocessor **32** with the mode and clock setting panel **48** to review the recorded data as it is displayed on the display **34**. The patient can then transcribe this information in a separate log book if desired. When the user visits the doctor, the doctor can download all the stored injection information into an external computer via the data I/O port **46** to produce a report similar to the one illustrated in FIG. **24**(*c*). The doctor can then review the data to spot trends and determine compliance with the medical regimen. If required, the doctor can update the program instructions in the pen-type injector **10** via the data I/O port **46** to provide reminder alarms at various times.

FIGS. **5** and **6** show detailed cross-sectional views of a preferred embodiment of a direct drive injection mechanism **20** as shown along the line **5—5** in FIG. **2**. FIGS. **7**(*a*)–**7**(*i*) show exploded views and details of the direct drive mechanism **20**. FIGS. **8–12** show various views that detail the drive mechanism **20** shown in FIGS. **5** and **6**. FIG. **13** is a cross-sectional view of the drive mechanism **20** along the line **13—13** shown in FIG. **6**. The drive mechanism **20** includes a dosage knob drive shaft **52**, a tension spring **54**, a lock nut **56**, a display seat **58**, an offset camshaft **60**, an electronics mount **62**, a ratchet spring **64**, a ratchet collar **66**, a drive calibrator **68**, a ratchet gear **70**, a synchronizer spring **72**, a stationary synchronizer **74**, a threaded drive shaft **76**,

a plunger **78**, an end cap **80**, a medication cartridge tensioner and synchronizer **82**, and a medication cartridge plunger **84** that are coupled as shown in FIGS. **5**–**12**.

The dosage knob drive shaft **52** is coupled to a splined dosage actuator **53** by a splined retainer **55** (see FIGS. **7**(*a*) and **7**(*d*)). The splines **96** of the dosage knob drive shaft **52** are timed to the splines **96**A of the splined dosage actuator **53** at a 45 degree rotational offset (alternative embodiments may use other angular rotational offsets). The offset is referenced by the pre-determined fixed location of the splined retainer **55** during assembly to the tubular end of the drive shaft **52**. The dosage knob drive shaft **52**, the dosage actuator **53**, the splined retainer **55** and the dosage actuator knob **12** form a sub-assembly. The sub-assembly is coupled to the threaded drive shaft **76** by a left-handed threaded locknut **56**. The threaded drive shaft **76** has a double keyway that runs the entire length of the threads on the threaded drive shaft **76** to allow the drive shaft **76** to move laterally in a keywayed bore **57** (see FIGS. **5**, **6** and **7**(*e*)–**7**(*i*)) of the dosage knob drive shaft **52** along the centerline axis of the sub-assembly when the dosage actuator **53** is rotated in a clockwise or counter-clockwise direction for the purpose of selecting a dosage setting. The double internal keyway in the splined end of the bore of the dosage knob drive shaft **52** is used to hold the threaded drive shaft **76** in a fixed position that prevents the threaded drive shaft **76** from rotating within the sub-assembly. The left-handed threaded locknut **56** is a retainer that prevents the threaded drive shaft **76** from traveling past a stop **59** located in the end of the dosage knob drive shaft **52** (see FIG. **7**(*e*)). The threaded locknut **56** also determines the end of the stroke for the threaded drive shaft **76**, which corresponds with a pre-determined position of the threaded drive shaft **76** to signify an empty medication cartridge.

The start button **38** is also coupled to the dosage actuator **53** to maintain the dosage actuator sub-assembly in a depressed position when the pen-type injector **10** is not being used, and to release the spring tensioned dosage actuator **53** and activate the microprocessor **32** when the pen-type injector **10** is to be used for an injection. Contained within the internal housing of the dosage actuator sub-assembly is a tension spring **54** that is securely attached to the interior of the sub-assembly by the actuator knob **12**. The purpose of the spring **54** is to hold the sub-assembly in a pre-determined tension to provide drive shaft dampening from the hydraulic loads produced during the injection cycle. All free tolerances in the dosage actuator sub-assembly are taken up by the tension spring **54** to maintain the sub-assembly in a stable configuration and to help insure injection dosage accuracy. When the starter button **38** is depressed, the synchronizer spring **72** displaces the entire dosage actuator sub-assembly along with the threaded drive shaft **76** and the drive calibrator **68** to move them into the activated position to select a dosage and inject the selected dosage of medication. Tension spring **54** and ratchet spring **64** provide shock damping for the dosage actuator sub-assembly, when it is ejected to and stopped at the activated position. The synchronizer spring **72** also facilitates maintaining the plunger **78** in a proper position with respect to the insulin cartridge plunger **84** when the pen-type injector **10** is not being used, so as to minimize the effects of fluid expansion or contraction that could draw air into the insulin cartridge **22** during storage.

The dosage knob drive shaft **52** that is assembled with the dosage actuator **53** has splines **96** which, when the dosage actuator **53** is in the depressed position, are locked in corresponding spline slots **98** of the injection mechanism housing **14** to prevent the dosage actuator **53**, the splined retainer **55**, the dosage actuator knob **12**, the dosage knob drive shaft **52** and the threaded drive shaft **76** from being rotated. When the dosage actuator **53** of the dosage knob sub-assembly is released by the start button **38**, the dosage actuator **53**, the dosage actuator knob **12** and the dosage drive shaft **52** move in a direction away from the medication cartridge **22**. The splines **96** then slide clear of the spline slots **98** so that the dosage actuator **53**, the dosage actuator knob **12**, the dosage knob drive shaft **52** and the threaded drive shaft **76** can be rotated as a single unit. This allows the relative positioning of the threaded drive calibrator **68** and the threaded drive shaft **76** to be adjusted, resulting in the drive calibrator **68** being advanced or retarded in position to adjust the dosage of medication that will be injected by the pen-type injector **10**.

The splines **96**A of the dosage actuator **53** are coupled to internal spline slots **100** of the offset cam collar **60** which is coupled to the counter **40** mounted on the electronics mount **62**. The offset cam collar **60** has cam lobes **102** that are in operative contact with rocker switches (contact switches or the like) on the counter **40**. When the dosage actuator **53** and dosage actuator knob **12** are rotated, the dosage knob drive shaft **52**, the splined retainer **55**, and the dosage actuator knob **12** sub-assembly rotate the offset camshaft **60** and the cam lobes **102** to actuate the rocker switches (not shown) to increment the counter **40** by one count per each predetermined angle of rotation of the dosage actuator **53**. The rotation of the dosage knob actuator knob **12** sub-assembly also changes the axial positioning of the threaded drive calibrator **68** relative to the threaded drive shaft **76**. This causes the drive calibrator **68** to advance or retard in position relative to the threaded drive shaft **76** depending on the direction of rotation of the dosage actuator **53** and dosage actuator **12** to adjust the dosage of the medication to be injected. In preferred embodiments, the pre-determined angle of rotation is 90 degrees (although larger or smaller angles may be used).

FIG. **7**(*c*) illustrates an alternative to the offset camshaft **60** and cam lobes **102** that are operatively coupled with the rocker switches (not shown) on the counter **40**. The alternative is a round drum **60**' having a plurality of thin bar code lines **102**' and thick bar code lines **102**" that are read by the counter through an optical sensor and light pipe (not shown). The lines **102**' and **102**" are grouped in pairs of one thin line **102**' next to one thick line **102**". The pairs are spaced at predetermined angles around the round drum **60**' to represent increments to increase or decrease the dosage amount to be injected. In preferred embodiments, the pairs of lines are spaced at 90° increments around the round drum **60**' (although larger or smaller increments may be used). In particular embodiments, the optical sensor senses one direction of rotation of the round drum **60**' by detecting a thin line **102**' followed by a thick line **102**" and then increments the counter **40** by one for each set of detected lines. Conversely, if the sensor detects a thick line **102**" followed by a thin line **102**', it determines that the rotation is in the opposite direction and decrements the counter **40** by one. In alternative embodiments, the lines may be a reflective material, rather than dark bar code lines. In further alternatives, the sensor may use infrared (IR) radiation or may use optical sensors that do not require light pipes.

The display seat **58** is adapted to hold the display **34** and the microprocessor **32**. The microprocessor **32** is coupled to the counter **40** that is mounted on the electronics mount **62** to determine the dosage of medication to be injected based upon the value in the counter **40**. The display seat **58** may

also be used to hold the clip **36** to allow the pen-type injector **10** to be carried like a pen.

The ratchet spring **64** is permanently attached to the interior of the injection mechanism housing **14**. The ratchet spring **64** applies pressure to the ratchet collar **66** which in turn applies pressure to the ratchet gear **70**. The ratchet gear **70** has teeth **104** that mate correspondingly with teeth **106** on the stationary synchronizer **74**. The synchronizer spring **72** applies a counter-pressure on the stationary synchronizer **74** to maintain the ratchet gear **70** and the stationary synchronizer **74** in contact with each other. Thus, when the actuator knob **12** is rotated, a ratchet noise is produced as the ratchet gear **70** is rotated relative to the stationary synchronizer **74**. Removal of the medication cartridge **22** reduces the pressure on synchronizer spring **72** so that the corresponding teeth **104** and **106** of the ratchet gear **70** and the stationary synchronizer **74** are disengaged. When the teeth **104** and **106** are disengaged, the actuator knob **12** can be rotated easily with minimal resistance, and the threaded drive shaft **76** can be withdrawn without resistance from the ratchet gear **70**.

The stationary synchronizer **74** also has splines **92** which are coupled to corresponding spline slots **94** in the injection mechanism housing **14** to prevent the stationary synchronizer **74** from rotating. However, the splines **92** are slidably coupled to the spline slots **94** so that the stationary synchronizer can slide back and forth within the injection mechanism housing **14**. This allows the medication cartridge **22** to increase the tension of the synchronizer spring **72** when the medication cartridge **22** is seated, and this increased tension causes the teeth **104** and **106** to engage.

FIGS. **7**(*a*), **7**(*d*)–(*i*) and **8**–**12** illustrate a drive mechanism utilizing a mono-directional ratchet gear **70** and a corresponding mono-directional stationary synchronizer **74**. The teeth **104** and **106** on the ratchet gear **70** and the synchronizer **74**, respectively are shaped to permit setting the dosage in only a single direction. Thus, if a user goes past the required dosage, they must either completely reset the pen or they must eject the currently set dosage. FIG. **7**(*b*) illustrates an alternative bi-directional ratchet gear **70**' and a corresponding bi-directional stationary synchronizer **74**' having teeth **104**' and **106**', respectively. The shape of the teeth **104**' and **106**' are symmetrical, as opposed to the right angular teeth **104** and **106** on the gear **70** and synchronizer **74**, to permit the dosage set by the counter **40** and displayed on the display **34** to be increased and decreased. Thus, users can correct the set dosage if they go past the desired dosage amount, without having to reset the pen or ejecting the incorrectly set dosage.

The drive calibrator **68** is threaded onto the threaded drive shaft **76** to determine the minimum and maximum positions in which the threaded drive shaft **76** can be moved to inject medication from the medication cartridge **22**. The drive calibrator **68** also performs as a rotational reference point to keep track of the incremental movement of the threaded drive shaft **76** so that the dosage of medication injected by the pen-type injector can be accurately determined. An end of the drive calibrator **68** has splines **88** that engage corresponding spline slots **90** in the end cap **80** to hold the drive calibrator **68** in a rotationally fixed position. The other side of the end cap **80** is coupled to the medication cartridge tensioner and synchronizer **82** which is used to secure a medication cartridge **22** to the injection housing **14**. The threaded drive shaft **76** is coupled to the medication cartridge plunger **84** to inject medication in the medication cartridge **22** when the actuator knob **12** is depressed.

The illustrated direct drive mechanism only requires a single complete depression of the actuator knob **12** to inject different set amounts of medication. The illustrated direct drive allows the user to accurately set various dosage values to be injected. The drive mechanism **20** is capable of providing dosage accuracies of between 0.1 to 1.0 unit increments. However, other dosage increments may be used. Moreover, in alternative embodiments, other suitable drive mechanisms can be used by the pen-type injector such as those disclosed in U.S. Pat. No. 5,114,406 issued May 19, 1992; U.S. Pat. No. 5,226,895 issued Jul. 13, 1993; and U.S. Pat. No. 5,279,585 issued Jan. 18, 1994.

A pen-type injector **200** in accordance with an embodiment of the present invention is shown in FIGS. **14** and **15**. The pen-type injector includes a blood characteristic monitor **202**, such as a glucose meter or the like, coupled to the injection mechanism housing **14**. This pen-type injector **200**, also includes a rotatable actuator knob **12**, a medication cartridge housing **16** and a protective needle cover **26** such as those discussed above with respect to the pen-type injector **10**. Instead of a window **18**, the medication cartridge housing **16** is transparent to allow easy viewing of the medication cartridge **22**. Moreover, the clip **36** is located on the protective needle cover **26** rather than the injection mechanism housing **14**. The pen-type injector **200** also uses a microprocessor **32** and a display **34**. However, in preferred embodiments the display is larger than in the previous embodiment to display more information, and both the display and the microprocessor **32** are coupled to the blood characteristic monitor **202**. The pen-type injector **200** with the blood characteristic monitor **202** allows the user to use a single, all-in-one device that keeps records, injects medication, and determines characteristics of a blood sample, and that can be used to produce reports similar to those shown in FIGS. **24**(*a*)–**24**(*d*).

FIG. **15** is a simplified block diagram of the pen-type injector **200** with a blood characteristic monitor **202**. The operation of the injection mechanisms and the related components is the same as described above in the previous embodiment. In the pen-type injector **202** the ROM **42** now stores additional programs to operate and control the blood characteristic monitor **202**. Moreover, the RAM **44** also stores results obtained from the blood characteristic monitor **202**. As shown in FIG. **14**, a test strip **204** for holding a blood sample is inserted into the test strip interface **206**. This activates the blood characteristic monitor **202** and the microprocessor **32**. The blood characteristic monitor **202** analyzes the blood characteristics and sends the analysis results to the microprocessor **32**, which displays the results on the display **34** and stores the results in the RAM **44** for later review.

In particular embodiments, the blood characteristic monitor **202** tests for the level of glucose in the blood. Preferably, the blood characteristic monitor **202** uses electrochemical sensor technology (i.e., the blood sample reacts with a chemical upon the application of an electrical current). The blood characteristic monitor **202** is periodically calibrated by a reusable code strip. To perform the analysis, the blood characteristic monitor utilizes a disposable (one time use) test strip **204**. The test strip **204** utilizes capillary action at the end of the test strip to draw in a small amount of blood (typically 3 micro-liters) into a reaction chamber (not shown) in the test strip interface **206** of the blood characteristic monitor **202**. When sufficient blood has been drawn into the reaction chamber, the test sequence begins and a blood glucose reading is displayed on the display **34** in approximately 60 seconds from the start of the testing sequence. In preferred embodiments, the blood characteristic monitor **202** provides blood glucose level results from 40–500 mg/dl (2.2–27.8 mmol/L); however, other ranges such as 20–600 mg/dl or the like may be used.

Operation of the blood characteristic monitor **202** is relatively simple. The operator fully inserts a test strip **204** into the test strip interface **206**. This turns on the microprocessor **32** and the blood characteristic monitor **202**. In preferred embodiments, the blood analysis mode is activated and the microprocessor **32** causes the display **34** to display the previous test result and the time of the last test event. The previous time and results are alternately flashed for 5 seconds (although longer or shorter times can be used). The user then places a blood sample (usually from a finger) on the end of the inserted test strip **204**, and the capillary action in the test strip **204** draws the sample into the reaction chamber of the test strip interface **206**. In preferred embodiments, the blood characteristic monitor **202** beeps, or provides some other audible indication, when a sufficient sample has been drawn into the reaction chamber. After the beep, the test is conducted and is typically completed in about 60 seconds. Once the test is completed, the results are displayed on the display **34** and simultaneously stored by the microprocessor **32** in the RAM **44** for later recall. Removal of the test strip **204** automatically turns off the blood characteristic monitor **202** and the microprocessor **32**. If the user fails to remove the test strip **204**, the microprocessor **32** sounds an alarm, and both the blood characteristic monitor **202** and the microprocessor **32** automatically turn off after 1 minute (although other time periods may be used). In alternative embodiments, other blood characteristic monitors may be used, such as a colormetric blood glucose meter, a dry membrane chemical reaction monitor or the like. Preferred embodiments of the present invention utilize blood characteristic monitors that use electro-chemical sensor techniques developed by Matsushita Electronics of Japan and distributed by Miles Laboratories, Inc. However, alternative embodiments, may utilize a dry chemical sensor with an electro-chemical membrane by either Boehringer Manheim Corp of Indianapolis, Ind. or MediSense of Cambridge Mass.

FIGS. **16**A–**16**B are a circuit schematic showing preferred embodiments of particular circuits used in the pen-type injector **200** with a blood characteristic monitor **202**. However, alternative embodiments, may use different circuit components or circuit implementations.

FIGS. **17** and **18** show an alternative embodiment of a pen-type injector **250** coupled with a blood characteristic monitor **202**. The pen-type injector **200** operates in a manner similar to the embodiments described-above with respect to FIGS. **14**–**16**B. However, the test strip interface **206** is 90° offset with respect to the embodiment of FIGS. **14**–**16**B, and the display **34** and the mode and clock setting panel **48** are arranged differently. FIG. **18** is a cross-sectional view of the pen-type injector **250** along the line **18**—**18** shown in FIG. **17**. This view illustrates that the pen-type injector **250** can use the drive mechanism **20** described above with respect to the embodiments of FIGS. **1**–**13**. Moreover, FIG. **18** illustrates the relative position of various internal components. For instance, the microprocessor **32**, the battery **50**, and a reaction chamber **252**.

FIGS. **19**–**21** show a preferred embodiment of a disposable needle **280** that substantially eliminates or reduces bleeding upon injection. The disposable needle **280** includes a threaded base **282**, a needle support **284**, a needle portion **286**, and a hollow cylindrical cover **288**. The threaded needle base **282** is adapted to be coupled to a pen-type injector as described above. However, in alternative embodiments, the needle base **282** may be attached by means of friction or the like, or the disposable needle **280** may be used with injectors other than pen-type injectors. A needle support **284** is coupled to the needle base **282** to hold the needle portion **286**. Also coupled to the needle support **284** and the needle base **282** is the hollow cylindrical cover **288**. The needle portion **286** is disposed inside the hollow cylindrical cover **288** such that the end of the needle portion **286** coupled to the needle support **284** cannot contact the skin during an injection. This prevents the needle support **284** from spreading the skin at the injection site. Spreading of the skin often results in bleeding. The needle portion **286** extends a sufficient distance beyond the hollow cylindrical cover **288** to allow for the proper administration of an injection. The hollow cylindrical cover helps the user insert the disposable needle **280** to the proper depth beneath the skin for an accurate injection. Moreover, the hollow cylindrical cover **288** tends to press the skin at the injection site together and this substantially eliminates or reduces bleeding at the injection site. The hollow cylindrical cover **288** also makes it easier for the user to attach and remove the disposable needle **280**, and decrease the probability of being pricked during attachment and removal of the disposable needle **280**.

FIG. **22** shows a blood characteristic monitor watch **300** in accordance with an embodiment of the present invention. The monitor watch **300** includes a blood characteristic monitor **302** and a wrist watch **304**. The blood characteristic monitor **302** is contained with the housing of the wrist watch **304** to provide a portable self-contained blood testing device that is convenient to use and can record detailed blood sample results, as well as injection administration information. This provides detailed reporting that a doctor can use to determine compliance with a prescribed medical regimen.

The wrist watch **304** resembles a conventional LCD watch, in size and shape, and includes a watch setting key pad **306**, a display **308**, and a function and power/data key pad **310** for controlling the blood characteristic monitor **302**. Inside the wrist watch **304** is a microprocessor **314** (see FIG. **23**) that couples the key pads **306** and **310** to the blood characteristic monitor **302** and the display **308**. The wrist watch **304** is secured to the user's wrist by a pair of watch straps **312**.

The blood characteristic monitor **302** includes a test strip interface **316** for receiving and analyzing a test strip **318**. The blood characteristic monitor is activated by either insertion of a test strip **318** or the power/data key pad **310**. The blood characteristic monitor **302** operates in a manner similar to that described above with respect to the embodiments of FIGS. **14**–**18**. The results of the blood analysis are stored by the microprocessor **314** and may be recalled for later review on the display **308**. In particular embodiments, the watch monitor **300** also includes a data input and output (I/O) port **320** which is activated and controlled by the microprocessor **314** and the power/data key pad **310** to upload program instructions and download information stored in a RAM **324** of the watch monitor **300**. In preferred embodiments, the data I/O port **320** uses infrared (IR) technology; however, other data port technologies, such as cables or the like, may be used.

FIG. **23** is a simplified block diagram of the watch monitor **300** with a blood characteristic monitor **302**. A test strip **318** is fully inserted into the test strip interface **316** to activate the blood characteristic monitor **302**. The blood characteristic monitor **302** analyzes the blood characteristics of the sample and sends the analysis results to the microprocessor **314**, which displays the results on the display **308**.

The microprocessor **314** is coupled to a ROM **322** and a RAM **324**. In preferred embodiments, the ROM **322** is an

EPROM and the RAM **324** is a static RAM; however, other comparable memory storage components may be used. The ROM **322** stores the programs used by the microprocessor **314** to determine various parameters, such as the correlation of results and the deviation from preset limits in a medical regimen, the date and the time, and how to report information to the user. The RAM **324** is used by the microprocessor **314** to store information about the blood analysis, as well as injections, for later recall by the user or the doctor. The microprocessor **314** also retrieves information from the RAM **324** so that a user or doctor can transcribe the stored information at a later time to determine compliance with the medical regimen and to spot trends requiring corrective action.

In preferred embodiments, the RAM **324** has a memory capacity for over 100 blood characteristic tests, 100 injection administration events, and memory to keep track of medication scheduling and special events. The microprocessor **314** is programmed to determine trends by comparing dosages administered by injections with the blood analysis results. These trends can be used by the microprocessor **314** to automatically recommend minor changes in the dosages within pre-programmed boundaries set by the doctor, or the trend results can be used by the doctor to directly adjust the dosages boundaries and the programs utilized by the microprocessor **314**. This provides the doctor with greater control and flexibility over the user's medical regimen.

In preferred embodiments, the microprocessor **314** is coupled to a data input and output (I/O) port **320**, and the user can download the stored information to an external computer (not shown) through the data I/O port **320**. The data I/O port **320** is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor.

A clock setting key pad **306** is also coupled to the microprocessor **314** to provide the user with the capability to store additional information, set the date and the time, or set alarms on an internal clock **326** to indicate when to perform another blood analysis or administer an injection. In alternative embodiments, the microprocessor **314** may perform the internal clock functions without the necessity of a separate internal clock **326**. The function key pad **310** also provide the capability to produce detailed reports and to interface with an external computer (not shown). The key pads **306** and **310** are used in conjunction with the display **308** to access the various modes and alarms utilizing methods typically employed to set the time on an LCD watch or the like. In preferred embodiments, the internal clock **326** of the watch monitor **300** is capable of multiple daily alarms, 12/24 hour formatting, and scrolling through a time zone map for easier record keeping during time zone changes.

The watch monitor **300** also includes a self contained battery and power convertor **328**. The battery is a small watch type battery, or in preferred embodiments, the battery is a lithium battery capable of providing power for up to 5 years.

In preferred embodiments, the blood characteristic monitor **302** analyses a blood sample to determine the level of glucose in the blood and the blood characteristic monitor **302** uses an electrochemical sensor technology such as described above with respect to the embodiments of FIGS. **14–18**. A disposable (one time use) test strip **318** uses capillary action at the end of the test strip **318** to draw in a small amount of blood (typically 3 microliters) into a reaction chamber (not shown) of the test strip interface **316**. When sufficient blood has been drawn into the reaction chamber, the testing sequence begins and a blood glucose reading is displayed on the display **308** in approximately 60 seconds from the start of the testing sequence. The blood characteristic monitor **302** provides blood glucose results from 40–500 mg/dl (2.2–27.8 mmol/L); however, other ranges may be used.

The blood characteristic monitor **302** is operated in substantially the same manner as described above with respect to the embodiments of FIGS. **14–18**. The operator fully inserts the test strip **318** into the test strip interface **316** to turn on the blood characteristic monitor **302** and access the microprocessor **314**. The blood characteristic analysis mode is activated and the microprocessor **314** causes the display **308** to display the previous test result and the time of the last test event. The user then places a blood sample (usually from a finger) on the end of the inserted test strip **318** which draws the sample into the reaction chamber of the test strip interface **316**. In preferred embodiments, the blood monitor **302** beeps, or provides some other audible indication, when a sufficient sample has been drawn into the reaction chamber. After the beep, the test is conducted and is typically completed in about 60 seconds. Once the test is completed, the results are displayed on the display **308** and simultaneously stored by the microprocessor **314** in the RAM **324** for later recall. Removal of the test strip **318** automatically turns off the blood monitor **302** and returns the microprocessor **314** and the watch monitor **300** to the watch mode. If the user fails to remove the test strip **318**, the microprocessor **314** sounds an alarm, and the blood monitor **302** is automatically turned off after 1 minute (although other time periods may be used). In alternative embodiments, other blood characteristic monitors may be used, such as a colormetric blood glucose meter, a dry membrane chemical reaction monitor or the like. Preferred embodiments utilize the above-described electro-chemical sensor technology in sensors produced by Matsushita Electronics of Japan and distributed by Miles Laboratories, Inc. However, alternative embodiments, may utilize a dry chemical sensor with an electro-chemical membrane by either Boehringer Manheim Corp of Indianapolis, Ind. or MediSense of Cambridge Mass.

FIGS. **24**(*a*)–**24**(*d*) illustrate typical reports that can be obtained via the data I/O port **320** from the watch monitor **300**. FIG. **24**(*a*) shows a summary report of the blood analysis performed by the blood characteristic monitor **302**. The readings are broken down into at least four basic time frames: breakfast, lunch, diner and snack. In preferred embodiments, the time frames may be further broken down into pre and post time frames. The report lists the number of blood analysis readings in each time frame, the standard deviation and the average value for the analyzed blood samples. FIG. **24**(*b*) shows a detailed report of all the individual blood analysis events. The report provides the date, the day, the time and the results for each analyzed blood sample. Thus, this portion of the report allows the doctor or user to spot anomalous readings. FIG. **24**(*c*) shows a detailed report on injections that have been administered and recorded by the user. The report provides the date, the day and the time of the injection. The report also recites how much of each type of insulin (regular (R) or intermediate (L)) was injected. This provides the doctor or user with information to compare blood analysis results with the amount of medication administered in the injection. FIG. **24**(*d*) shows a detailed report on markers that are set and recorded by the user to indicate certain events or changes from the regular medical regimen. This provides the doctor or user with information that can aid in understanding and correlating otherwise anomalous results.

In preferred embodiments, test results can be deleted by pressing the delete button on the function key pad **310**. This removes the results from the blood test average, for calibration or control test results, to prevent skewing the actual analysis information. The marker key on the function keypad **310** gives the user the option to store important information along with results already stored in the RAM **324**. This can aid the user in recalling specific events or types of events that establish a trend. The marks are inserted by pressing the mark key and turning the blood characteristic monitor **302** off. Markers can be used to identify meal times, exercise times, injection events, or special circumstances and changes from the normal regimen.

In alternative embodiments, the watch monitor **300** can be used with a pen-type injector **10** described in the embodiment discussed above with respect to FIGS. **1–13**. The data I/O port **320** of the watch monitor **300** can be utilized to download the injection information stored in the RAM **44** of the pen-injector **10**. This simplifies the input of relevant injection data into the watch monitor **300**.

FIGS. **25**(*a*)–**25**(*e*) show a pen-type injector **400** with a blood characteristic monitor in accordance with an embodiment of the present invention. The pen-type injector **400** operates in a manner similar to the embodiments described-above with respect to FIGS. **14–18** and has the capabilities to provide the reports described in FIGS. **24**(*a*)–**24**(*d*).

The pen-type injector **400** includes a detachable, protective cover and cap **402** that contains a storage area **404** for holding test strips **406** and a finger lancer mechanism **408** for obtaining a blood sample from the users finger. The cap **402** is snap fitted to the pen-type injector **400**. However, in alternative embodiments, the cap **402** may be coupled to the pen-type injector **400** by different methods, such as hinges, adhesives, friction, detentes or the like.

A closed end **410** of the cap **402** supports a pen clip **412** and is snap fitted to the cap **402** to close off the end of the cap **402**. When the closed end **410** is removed, the user has easy access to the storage area **404** and the finger lancer mechanism **408**. In alternative embodiments, the closed end **410** of the cap **402** may be coupled to the cap **402** by different methods, such as hinges, adhesives, friction, detentes or the like.

As shown in FIGS. **25**(*a*), (*b*) and (*e*), the storage area **404** includes a leaf spring mechanism **414** and a slidable test strip supply button **416**. Test strips **406** are loaded into the storage area **404** of the cap **402** through the opening produced when the closed end **410** of the cap **402** is removed. The user presses the leaf spring mechanism **414** down towards the center of the cap **402** away from the supply button **416**, and the test strips **406** are then inserted between the leaf spring mechanism **414** and the supply button **416**. The leaf spring **414** places the test strips **406** under sufficient pressure such that a single test strip **406** is ejected from the end of the cap **402** next to the pen-type injector **400** whenever the supply button **416** is slid towards the open end of the cap **402**. Once a test strip **406** is ejected, the supply button **416** is slid back towards the closed end **410** of the cap **402** and the next test strip **406** is pressed into position to be ejected with the next sliding of the supply button **416**. In alternative embodiments, different test strip **406** delivery systems may be used, such as a built in storage vial from which the user grasps and removes a single test strip **406**, an electronic motorized test strip dispenser, a container for holding manufacturer's test strip shipment containers or the like.

As shown in FIG. **25**(*a*), the finger lancer mechanism **408** includes a release button **418**, a tensioning and loading button **420**, a spring **422** and a finger lancer **424** (shown in dashed lines in FIG. **25**(*a*)) and a form fitted lancer puncture site **426**. Extra finger lancers **424** can be stored in a small storage compartment **428** in the cap **402** (as shown in FIG. **25**(*e*)). Access to the storage compartment **428** is through the end of the cap **402** when the closed end **410** of the cap **402** is removed.

In preferred embodiments, a lancer is mounted to a lancer collet (not shown) at the end of the spring **424**. When the loading button **420** is slid all the way towards the form fitted puncture site **426** it is locked in position and the lancer collet is loosened to allow removal of a used finger lancer **424** and the insertion of a new finger lancer **424**. Once a new finger lancer **424** has been inserted into the lancer collet, the release button **418** is depressed and the loading button slides back to a neutral position as the tension on spring **422** is released.

To lance the finger and obtain a blood sample, the loading button **420** is slid towards the release button **418** until it is locked in position and a second lancing spring **430** is placed under sufficient pressure to drive the finger lancer **424** to puncture the finger of a user. Next, a user's finger is placed along side the form fitted puncture site **426**. The user then depresses the release button **418**. As the release button **418** is depressed the lancing spring **430** drives the finger lancer **424** forward to puncture the user's finger. After the finger lancer **424** is driven towards the puncture site **426**, the spring **422** is placed under compressive tension to stop the forward movement of the finger lancer **424** after it has punctured the finger of the user. Then the spring **422** pushes the finger lancer **424** back inside the cap and away from the puncture site **426** until the loading button **420** is in a neutral position between the spring **422** and the lancer spring **430**. After the user's finger is lanced, the user will place a drop of blood on a test strip **406** mounted in the blood monitor of the pen-type injector **400**.

The pen-type injector **400** also includes an on/off button **432**, a mode button **434**, a function button **436**, a start button **438**, an actuator dosage knob **440**, a display **442**, a test strip interface **444** and a data port **446** that are all mounted in an injector housing **448**. In preferred embodiments, the on/off button **432**, mode button **434**, function button **436**, start button **438** and actuator dosage knob **440** operate in a manner similar to that described in the previous embodiments illustrated in FIGS. **1–24**(*d*). Also, the display **442**, the test strip interface **444** and data port **446** may use the same technology as described in the previous embodiments illustrated in FIGS. **1–24**(*d*).

The pen-type injector **400** further includes a test strip code key interface **450** for receiving a code key **452** (see the cut-away section in FIG. **25**(*b*)) that calibrates the blood monitor of the pen-type injector **400** for use with the batch of test strips **406** currently being stored in the storage area **404**. In alternative embodiments, the blood monitor may be calibrated by accessing calibration codes that are stored in the memory of the pen-type injector **400**.

The user depresses the on/off button **432** to activate the pen-type injector for either a blood test, to review data stored in the memory of the pen-type injector **400** or to transfer data between the pen-type injector **400** and an external computer (not shown). To deactivate the pen-type injector **400**, the user depresses the on/off button **432** again. In preferred embodiments, if no functions or tests are performed within 1 minute (although longer or shorter times may be used), the pen-type injector **400** enters a "sleep mode" to conserve power. In the "sleep mode" the pen-type injector **400** can be

reactivated by depressing a function **436** or mode **434** button, depression of the start button **438** or insertion of a test strip **406**.

To perform a blood test, a user inserts a code key **452** into the code key interface **450** to calibrate the blood monitor of the pen-type injector **400** (see the cut-away of FIG. **25**(*b*)). The code key **452** typically remains in the code key interface **450** until the current batch of test strips **406** in the storage area **404** are used up and a new batch is then inserted in the storage area **404**. In alternative embodiments, the pen-type injector **400** may use a different calibration method, instead of a code key, such as a bar code reader, a data uplink or the like to provide calibration information for the blood monitor of the pen-type injector **400**.

Once the blood monitor is calibrated, the user inserts a test strip **406** into the test strip interface **444**. The blood monitor beeps or provides a visual indication on the display **442** that the test strip **406** has been properly inserted and that the blood monitor is now ready to perform a blood test. The user then applies a drop of blood to the end of the test strip **406**. Capillary action or target membrane area saturation draws the blood up into the test strip interface **444**. When sufficient blood has been drawn into the interface **444**, the blood monitor again provides a beep or visual indication on the display **442** and commences the test. After the test is completed, the blood monitor provides a beep and visually displays the results on the display **442**. If the results are acceptable, they are stored in memory, along with the date and time for later recall. If the test results were erroneous, an error message will be displayed on the display **444** and these will be stored in memory, unless the user deletes the results and error message within 1 minute (although longer or shorter times may be used) of the test being completed.

The user can use the mode button **434** and the function button **436** to program the pen-type injector **400**. For example, the buttons can be used to set alarms or reminders, used to annotate stored test and injection data, used to set the time and date, or used to download data and upload instructions through the data port **446**. The data port **446** utilizes a wired connection, such as an RS-232 standard to transfer data and instructions back and forth between the pen-type injector **400** and a computer (not shown). However, alternative embodiments can use other data transfer technology, such as infrared, radio waves or the like. In further alternatives, a bar code reader may be used.

To give an injection, the user depresses the start button **438** to release the dosage actuator knob **440**. The user then rotates the actuator knob **440** to select a small dosage and performs an "air shot" to remove any air from the needle **28** and cartridge **22**. If the user desires, the dosage amount and injection information for the air shot may be deleted before it is stored in memory or the injection may be marked as an "air shot." After the "air shot," the desired dosage is selected and the user performs an injection in a manner similar to that described in the embodiments illustrated in FIGS. **1–18**. After the injection, the user can use the mode button **434** and function button **436** to annotate the injection information. The injection dosage, annotated information, date and time are stored and can be used to display or download the stored data to produce reports similar to those illustrated in FIGS. **24**(*a*)–**24**(*d*).

The housing **448** of the pen-type injector **400** is ergonomically formed and shaped to fit easily in the user's hand for both blood characteristic testing and injections. The housing **448** also includes a gripping section **454** to facilitate control of the pen-type injector **400**. In preferred

embodiments, the housing **448** is formed from a plastic material and the gripping section **454** is formed by raised plastic ridges. In alternative embodiments, the housing **448** may be made out of different materials, such as metal, glass composites or the like, and the gripping section may use different textures or materials that are applied to the gripping section **454** of the pen-type injector **400**.

As shown in FIG. **25**(*b*), the housing **448** of the pen-type injector also includes a battery compartment for holding two disk shaped batteries, such as are commonly used in calculators, watches and blood monitoring equipment. However, alternative embodiments may utilize different types of batteries or external power sources. Location **458** represents a location where, for example, a jack for an external power source such as an AC adapter may be placed. In alternative embodiments, a different type of data port **446** may be placed in location **458**. For example, a bar code reader or IR port could be placed in this location **458** for easy uploading and downloading of data.

FIGS. **26**(*a*)–**26**(*c*) show a pen-type injector **500** in accordance with an embodiment of the present invention. The pen-type injector **500** operates in a manner similar to the embodiments described-above with respect to FIGS. **1–13** and has the capabilities to provide the report described in FIG. **24**(*c*).

The pen-type injector **500** includes a cap **502** for easy removal and covering of the needle **28** and the pen-type injector **500**. In the illustrated embodiment, the mode button **504** and the function button **506** have been placed at the end of the pen-type injector **500** near a dosage knob **508**. This provides additional space on a pen clip **510** for a larger display **512** that is easier to read by elderly users or patients that have difficulty reading small numbers. The pen clip **S10** also contains a battery compartment **514** for holding the batteries required to operate the pen-type injector **500**. Locating the battery compartment **514** on the pen clip **514** facilitates changing of the batteries, since it is readily accessible and the user can use a screwdriver, nail file, dime or the like to unscrew the cover of the battery compartment **514**. The pen-type injector **500** also includes a position indicator **516** that aids the user in setting the dosage. The indicator **516** represents one dosage increment (or decrement) each time the indentations **518** are rotated past the indicator **516**. In alternative embodiments, audio indicators or other visual indicators may be used.

Various aspects of the illustrated embodiments may be combined in different ways. For example, the reports generated by the watch monitor **300** may be produced by the pen-type injector **10**, the combination pen-type injector **200**, the combination pen-type injector **400**, and the pen-type injector **500**. The various features such as alarms, test strip storage and lancers may also be combined with the various embodiments.

Also various other types of medication delivery devices, such as medication pumps, jet injectors, inhalers, sprays or the like may be used. For example, particular embodiments may use a medication pump injection mechanism that is worn by the patient during the day, and which has a receptacle for storing fluid that is injected manually or by a pre-set timed sequence. The medication is delivered through a tube that is attached to the pump delivery mechanism at one end and a shunt that is temporarily connected to the patient's body at the other end of the tube. The medication pump is combined with a processor so that insulin or the like is delivered by the pump and the processor stores relevant information about the medication delivered. Also, the pro-

cessor is coupled to a characteristic monitor, which is used to determine the characteristics of a sample from the patient and to store the information with the processor coupled to the medication pump. In particular embodiments, the medication pump can use removable pre-measured, pre-filled disposable or rechargeable ampules of medication.

In another alternative embodiment, a portable, hand-held pneumatic or compression spring-assisted medical injection delivery mechanism such as a "jet" injector or the like is used to inject a medication. Particular embodiments use a needle or high pressure needle-less stream that pierces the skin at the injection site to deliver the injection subcutaneously or intermuscularly. In further embodiments, the injection device may use a needle which allows the user to extract a measurable amount of medication from a storage canister or ampule, and receive it in a delivery chamber of the device that is similar to a syringe chamber. Alternatively, the injection device can use removable pre-measured, pre-filled disposable or rechargeable ampules of medication. In preferred embodiments, the injection device can also be coupled to a processor for storing information about the injection and a characteristic monitor for analyzing and storing characteristics from a sample taken from the patient's body.

In another alternative embodiment, a portable, hand-held medical nasal inhaler or spray which has a receptacle capable of holding a pre-filled cartridge, vial, or pressurized container of mediation is used to deliver a dosage of medication. Particular embodiments, may use a manual or an automatically regulated and controlled delivery mechanism for administering the medication via drip or atomized nasal spray. The inhaler or spray can use removable pre-measured, pre-filled disposable or rechargeable ampules of medication. The inhaler or spray is coupled to a processor to determine and store the amount of medication that is delivered. In preferred embodiments, the inhaler or spray is also coupled to a characteristic monitor for analyzing and storing characteristics from a sample taken from the patient's body.

The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. A medical monitor, comprising:

a portable housing;

a characteristic monitor contained in the portable housing for analyzing a characteristic sample;

a processor coupled to the characteristic monitor, wherein the processor includes determining means for determining characteristics based on the analyzed characteristic sample from the characteristic monitor; and

a data port coupled to the processor, wherein the data port includes transferring means for transferring data and program instructions from a medication delivery device to the processor,

wherein the processor includes means for using the characteristics and the data from the medication delivery device to compare the characteristics and data to determine if the medical regimen is correct and whether modifications to the medical regimen are required.

2. A medical monitor according to claim **1**, wherein transferring means of the data port coupled to the processor is used to transfer data from the processor to the medication delivery device.

3. A medical monitor according to claim **2**, wherein the transferring means of the data port uses infrared energy to transfer data from the processor to the medication delivery device.

4. A medical monitor according to claim **1**, further including a display device coupled to the processor to display the characteristics determined by the processor.

5. A medical monitor according to claim **1**, further including a clock circuit to determine a time and date.

6. A medical monitor according to claim **5**, wherein the clock circuit further includes means to provide an alarm indication at a predetermined time.

7. A medical monitor according to claim **1**, wherein the transferring means of the data port uses infrared energy to transfer information from the medication delivery device to the processor.

8. A medical monitor according to claim **1**, further including a memory storage device coupled to the processor for storing the characteristics determined by the processor.

9. A medical monitor according to claim **1**, wherein the characteristic monitor measures blood characteristics.

10. A medical monitor according to claim **1**, wherein the medication delivery device is selected from a group consisting of pen-type injectors, infusion pumps and inhalers.

11. A medical monitor, comprising:

a portable housing;

a characteristic monitor contained in the portable housing for analyzing a characteristic sample;

a processor coupled to the characteristic monitor, wherein the processor includes determining means for determining characteristics based on the analyzed characteristic sample from the characteristic monitor; and

a data port coupled to the processor, wherein the data port includes transferring means for transferring the characteristics from the processor to a medication delivery device and to receive data from the medication delivery device,

wherein the processor include means for using the characteristics and the data from the medication delivery device to compare the characteristics and data to determine if the medical regimen is correct and whether modifications to the medical regimen are required.

12. A medical monitor according to claim **11**, wherein the transferring means of the data port coupled to the processor is used to transfer data from the medication delivery device to the processor.

13. A medical monitor according to claim **12**, wherein the transferring means of the data port uses infrared energy to transfer data to the processor from the medication delivery device.

14. A medical monitor according to claim **11**, further including a display device coupled to the processor to display the characteristics determined by the processor.

15. A medical monitor according to claim **11**, further including a clock circuit to determine a time and date.

16. A medical monitor according to claim **15**, wherein the clock circuit further includes means to provide an alarm indication at a predetermined time.

17. A medical monitor according to claim **11**, wherein the transferring means of the data port uses infrared energy to transfer characteristics to the medication delivery device from the processor.

18. A medical monitor according to claim **11**, further including a memory storage device coupled to the processor for storing the characteristics determined by the processor.

19. A medical monitor according to claim **11**, wherein the characteristic monitor measures blood characteristics.

20. A medical monitor according to claim **11**, wherein the medication delivery device is selected from the group consisting of pen-type injectors, infusion pumps and inhalers.

21. A medical monitor to monitor a medical regimen, the medical monitor comprising:

a characteristic monitor for analyzing a characteristic sample;

a processor coupled to the characteristic monitor, wherein the processor includes determining means for determining characteristics based on the analyzed characteristic sample from the characteristic monitor; and

a data port coupled to the processor, wherein the data port includes transferring means for transferring the characteristics from the processor to medication delivery device and to receive data or program instructions from the medication delivery device,

wherein the processor includes means for using the characteristics and the data from the medication delivery device to compare the characteristics and data to determine if the medical regimen is correct and whether modifications to the medical regimen are required.

22. A medical monitor according to claim **21**, further including a memory storage device coupled to the processor for storing the characteristics determined by the processor and the data or program instructions from the medication delivery device.

23. A medical monitor according to claim **21**, further including a display device coupled to the processor to display the characteristics determined by the processor and the data from the medication delivery device.

24. A medical monitor according to claim **21**, further including a clock circuit to determine a time and date.

25. A medical monitor according to claim **21**, further including means to provide an alarm indication at a predetermined time or when a change to a medical regimen is determined.

26. A medical monitor according to claim **21**, wherein the transferring means of the data port uses infrared energy to transfer characteristics to the medication delivery device from the processor and to transfer data or program instructions to the processor from the medication delivery device.

27. A medical monitor according to claim **21**, wherein the characteristic monitor measures blood characteristics.

28. A medical monitor according to claim **21**, wherein the medication delivery device is selected from a group consisting of pen-type injectors, infusion pumps and inhalers.

* * * * *

EXHIBIT C

US005957895A

United States Patent [19]

Sage et al.

[11] Patent Number: 5,957,895

[45] Date of Patent: Sep. 28, 1999

[54] **LOW-PROFILE AUTOMATIC INJECTION DEVICE WITH SELF-EMPTYING RESERVOIR**

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[73] Assignee: **Becton Dickinson and Company**, Franklin Lakes, N.J.

[21] Appl. No.: **09/027,291**

[22] Filed: **Feb. 20, 1998**

[51] **Int. Cl.**[6] **A61M 5/178**

[52] **U.S. Cl.** **604/181**; 604/131; 604/134; 604/185

[58] **Field of Search** 604/181, 183–185, 604/131, 132, 187, 133, 134, 136

[56] **References Cited**

U.S. PATENT DOCUMENTS

718,837	7/1903	Cook .
1,102,953	7/1914	Rabat .
1,288,174	12/1918	Pittenger .
2,408,323	9/1946	Lockhart .
2,545,017	3/1951	Billingsley .
2,576,951	12/1951	Lockhart .
2,589,426	3/1952	Ogle .
2,605,765	8/1952	Kollsman .
2,667,164	1/1954	Smith .
2,667,165	1/1954	Smith .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0258073	6/1987	European Pat. Off. .
0272530	12/1987	European Pat. Off. .
0388169	9/1990	European Pat. Off. .
0638324	2/1995	European Pat. Off. .
2240025	7/1973	France .
2243705	9/1973	France .
2599976	6/1986	France .
3275073	12/1991	Japan .
1537267	1/1990	Russian Federation .
8912473	12/1989	WIPO .
9100753	1/1991	WIPO .
9211879	7/1992	WIPO .
9323096	11/1993	WIPO .
9407562	4/1994	WIPO .
9503078	2/1995	WIPO .
9513838	5/1995	WIPO .
9637245	11/1996	WIPO .
9709025	3/1997	WIPO .
9710012	3/1997	WIPO .
9721457	6/1997	WIPO .

OTHER PUBLICATIONS

"A Simple Solution for Complex Drug Delivery", Elan Pharmaceutical Technologies (1997).

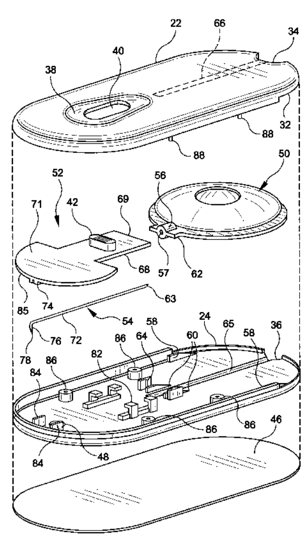
Bruce D. Wigness et al., "The Spring–Driven Implantable Pump: A Low–Cost Alternative", *ASAIO Journal* 1992, pp. M454–M457.

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Donna R. Fugit, Ph.D.

[57] **ABSTRACT**

A device for delivering a liquid theraputic preparation into the body of a patient by injection into or through the skin of the patient comprises a low-profile housing having a bottom surface adapted to be brought into contact with the skin of the patient. A reservoir is disposed within the housing for containing a liquid theraputic preparation to be administered. An injection needle is disposed generally horizontally in the housing, and is adapted to communicate with the reservoir. The injection needle has a bent injection end which is adapted to project through a needle aperture in the bottom surface of the housing. A movable needle carrier is disposed in the housing for carrying the injection needle and for causing the injection end of the needle to project through the needle aperture upon movement of the needle carrier. The needle carrier and the injection needle are disposed in a side-by-side relationship with the reservoir in the housing in order to minimize the height of the housing above the bottom surface. As a result, the housing is sufficiently low in height to allow the device to be worn inconspicuously under the clothing of the patient.

20 Claims, 13 Drawing Sheets



U.S. PATENT DOCUMENTS

2,769,443	11/1956	Dunmire .
2,871,856	2/1959	Steiner .
2,880,723	4/1959	Adams .
3,082,681	3/1963	Petersen .
3,172,200	3/1965	Ream .
3,173,200	3/1965	Dunmire et al. .
3,238,784	3/1966	Dorsey et al. .
3,306,290	2/1967	Weltman .
3,469,578	9/1969	Bierman .
3,496,937	2/1970	Balson .
3,506,005	4/1970	Gilio et al. .
3,507,278	4/1970	Werding .
3,563,373	2/1971	Paulson .
3,587,575	6/1971	Lichtenstein .
3,677,444	7/1972	Merrill .
3,923,060	12/1975	Ellinwood, Jr. .
3,941,131	3/1976	Ogle .
3,951,147	4/1976	Tucker et al. .
3,993,069	11/1976	Buckles et al. .
4,013,073	3/1977	Cunningham .
4,044,758	8/1977	Patel .
4,140,117	2/1979	Buckles et al. .
4,182,325	1/1980	Camp .
4,188,950	2/1980	Wardlaw .
4,193,397	3/1980	Tucker et al. .
4,194,505	3/1980	Schmitz .
4,196,732	4/1980	Wardlaw .
4,201,207	5/1980	Buckles et al. .
4,214,584	7/1980	Smirnov et al. .
4,227,528	10/1980	Wardlaw .
4,235,234	11/1980	Whitney et al. .
4,258,711	3/1981	Tucker et al. .
4,258,713	3/1981	Wardlaw .
4,270,533	6/1981	Andreas .
4,282,986	8/1981	af Ekenstam et al. .
4,299,220	11/1981	Dorman .
4,340,048	7/1982	Eckenhoff .
4,373,527	2/1983	Fischell .
4,378,015	3/1983	Wardlaw .
4,386,929	6/1983	Peery et al. .
4,419,096	12/1983	Leeper et al. .
4,468,220	8/1984	Willbanks .
4,487,603	12/1984	Harris .
4,522,622	6/1985	Peery et al. .
4,525,164	6/1985	Loeb et al. .
4,548,601	10/1985	Lary .
4,552,561	11/1985	Eckenhof et al. .
4,559,039	12/1985	Ash et al. .
4,601,707	7/1986	Albisser et al. .
4,619,652	10/1986	Eckenhoff et al. .
4,645,495	2/1987	Vaillancourt .
4,684,365	8/1987	Reinicke .
4,692,151	9/1987	Blackman .
4,697,622	10/1987	Swift et al. .
4,710,176	12/1987	Quick .
4,714,733	12/1987	Itoh et al. .
4,718,893	1/1988	Dorman et al. .
4,722,732	2/1988	Martin .
4,728,320	3/1988	Chen .
4,734,092	3/1988	Millerd .
4,741,733	5/1988	Winchell et al. .
4,747,831	5/1988	Kulli .
4,753,651	6/1988	Eckenhoff .
4,767,413	8/1988	Haber et al. .
4,769,008	9/1988	Hessel .
4,772,263	9/1988	Dorman et al. .
4,781,688	11/1988	Thoma et al. .
4,813,426	3/1989	Haber et al. .
4,850,961	7/1989	Wanderer et al. .
4,883,473	11/1989	Thomas .
4,886,499	12/1989	Cirelli et al. .
4,894,054	1/1990	Miskinyar .
4,900,310	2/1990	Ogle, II .
4,902,278	2/1990	Maget et al. .
4,904,239	2/1990	Winchell et al. .
4,909,790	3/1990	Tsujikawa et al. .
4,915,693	4/1990	Hessel .
4,955,871	9/1990	Thomas .
4,968,301	11/1990	di Palma et al. .
4,994,042	2/1991	Vadher .
4,998,918	3/1991	Mimura .
5,011,477	4/1991	Winchell et al. .
5,019,047	5/1991	Kriesel .
5,019,048	5/1991	Margolin .
5,041,094	8/1991	Perego et al. .
5,045,064	9/1991	Idriss .
5,061,249	10/1991	Campbell .
5,062,834	11/1991	Gross et al. .
5,080,652	1/1992	Sancoff et al. .
5,090,963	2/1992	Gross et al. .
5,120,315	6/1992	Hessel .
5,122,116	6/1992	Kriesel et al. .
5,135,499	8/1992	Tafani et al. .
5,156,591	10/1992	Gross et al. .
5,167,631	12/1992	Thompson et al. .
5,169,389	12/1992	Kriesel .
5,178,610	1/1993	Tsujikawa et al. .
5,201,718	4/1993	Whisson .
5,205,820	4/1993	Kriesel .
5,248,300	9/1993	Bryant et al. .
5,248,303	9/1993	Margolin .
5,263,935	11/1993	Hessel .
5,263,940	11/1993	Kriesel .
5,267,957	12/1993	Kriesel et al. .
5,267,963	12/1993	Bachynsky .
5,279,544	1/1994	Gross et al. .
5,279,558	1/1994	Kriesel .
5,284,481	2/1994	Soika et al. .
5,298,025	3/1994	Hessel et al. .
5,312,364	5/1994	Jacobs .
5,318,557	6/1994	Gross .
5,328,464	7/1994	Kriesel et al. .
5,334,197	8/1994	Kriesel et al. .
5,336,188	8/1994	Kriesel .
5,354,264	10/1994	Bae et al. .
5,354,278	10/1994	Kriesel .
5,364,373	11/1994	Waskonig et al. .
5,374,256	12/1994	Kriesel .
5,398,851	3/1995	Sancoff et al. .
5,411,480	5/1995	Kriesel .
5,419,771	5/1995	Kriesel .
5,425,722	6/1995	Whisson .
5,433,709	7/1995	Kriesel .
5,468,226	11/1995	Kriesel .
5,478,324	12/1995	Meyer .
5,484,415	1/1996	Kriesel .
5,492,533	2/1996	Kriesel .
5,498,245	3/1996	Whisson .
5,514,090	5/1996	Kriesel et al. .
5,527,287	6/1996	Miskinyar .
5,527,288	6/1996	Gross et al. .
5,529,214	6/1996	Lasonde et al. .
5,545,139	8/1996	Kriesel .
5,551,849	9/1996	Christiansen .
5,553,741	9/1996	Sancoff et al. .
5,558,255	9/1996	Sancoff et al. .
5,569,192	10/1996	van der Wal .
5,571,261	11/1996	Sancoff et al. .
5,578,005	11/1996	Sancoff et al. .
5,616,132	4/1997	Newman .
5,620,420	4/1997	Kriesel .
5,645,536	7/1997	Whisson .

5,649,910	7/1997	Kriesel et al. .
5,649,912	7/1997	Peterson .
5,656,032	8/1997	Kriesel et al. .
5,693,018	12/1997	Kriesel et al. .
5,693,019	12/1997	Kriesel .
5,700,244	12/1997	Kriesel .
5,700,245	12/1997	Sancoff et al. .
5,704,520	1/1998	Gross .
5,707,361	1/1998	Slettenmark .
5,707,499	1/1998	Joshi et al. .
5,716,343	2/1998	Kriesel et al. .
5,720,729	2/1998	Kriesel .
5,735,818	4/1998	Kriesel et al. .
5,738,657	4/1998	Bryant et al. .
5,741,242	4/1998	Kriesel .
5,743,879	4/1998	Kriesel .
5,776,103	7/1998	Kriesel et al. .
5,779,676	7/1998	Kriesel et al. .
5,785,688	7/1998	Joshi et al. .

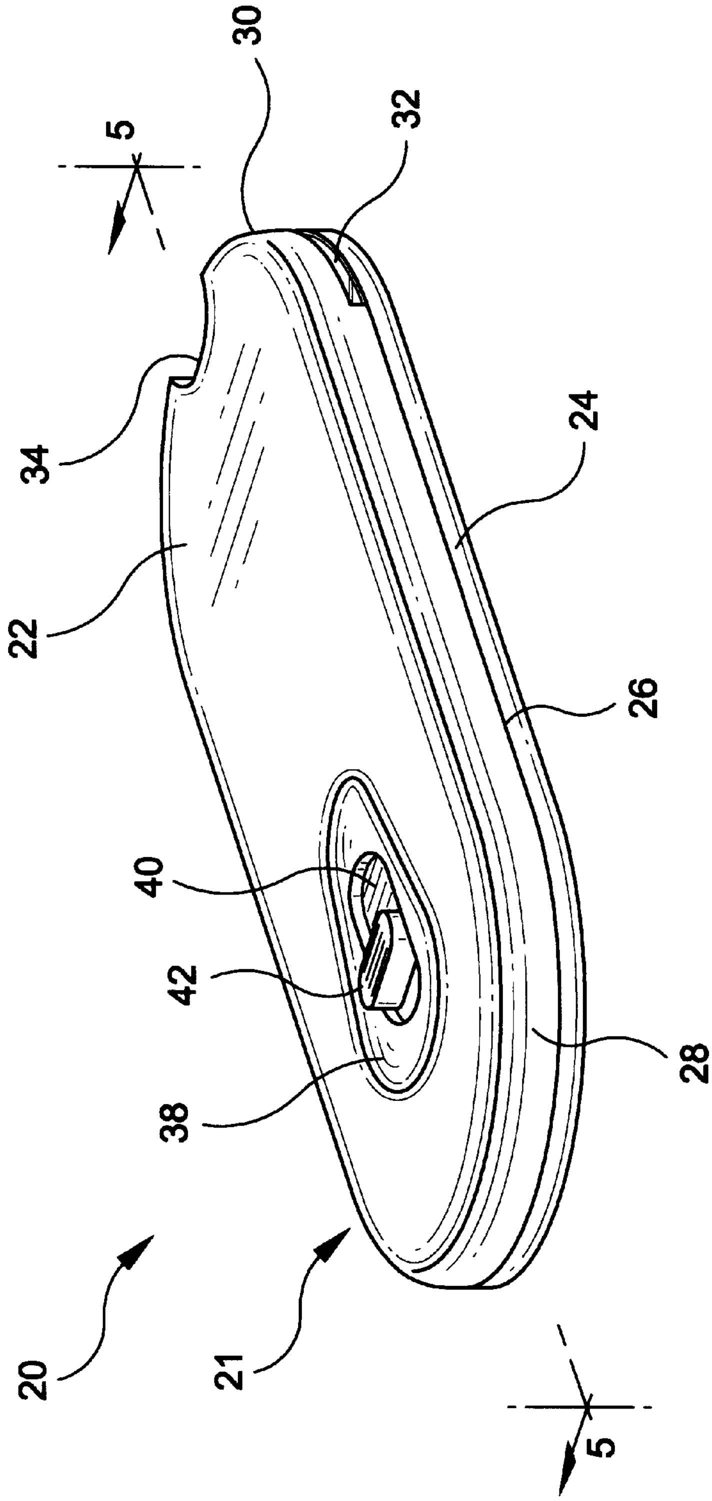


FIG-1

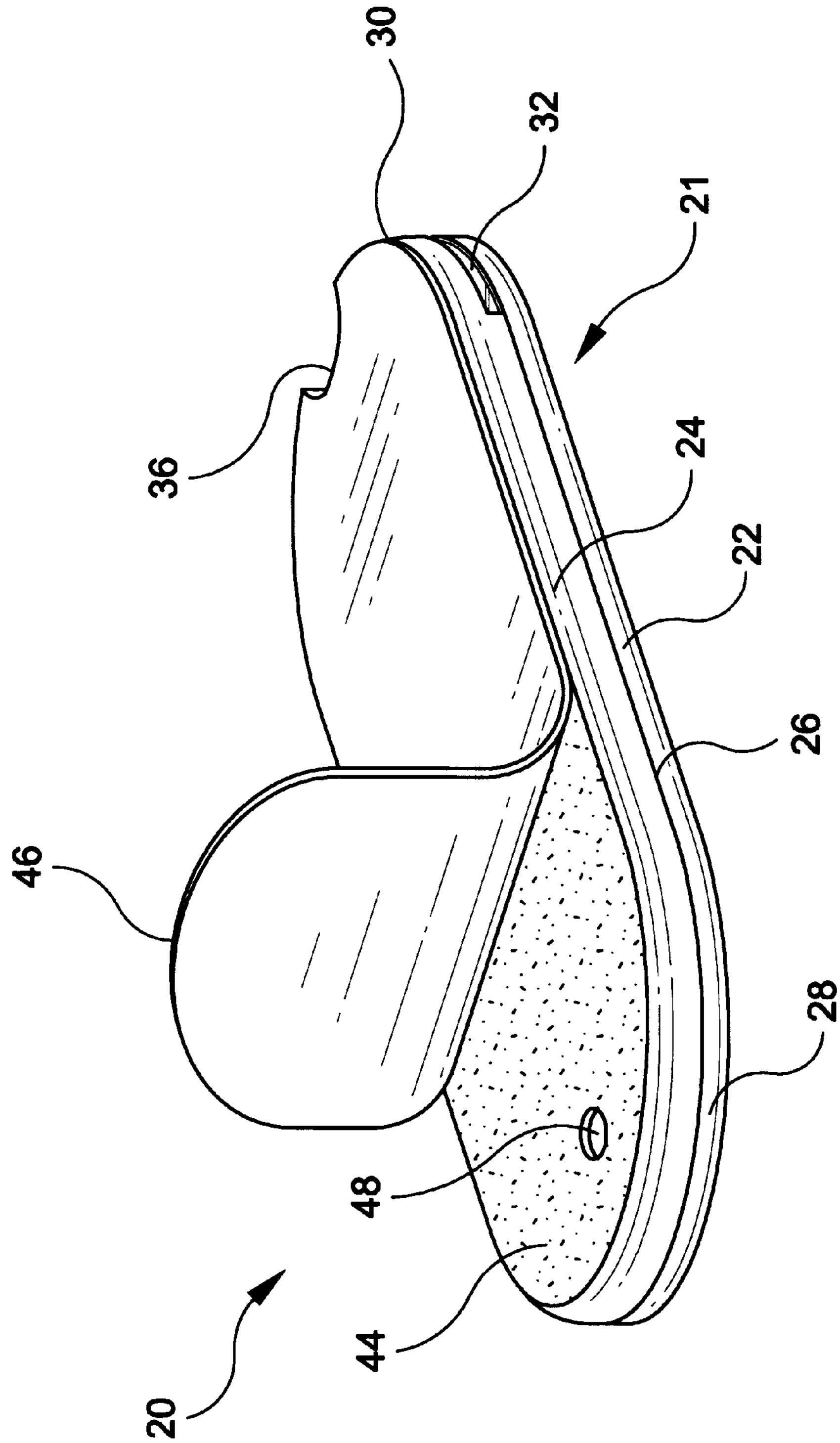


FIG-2

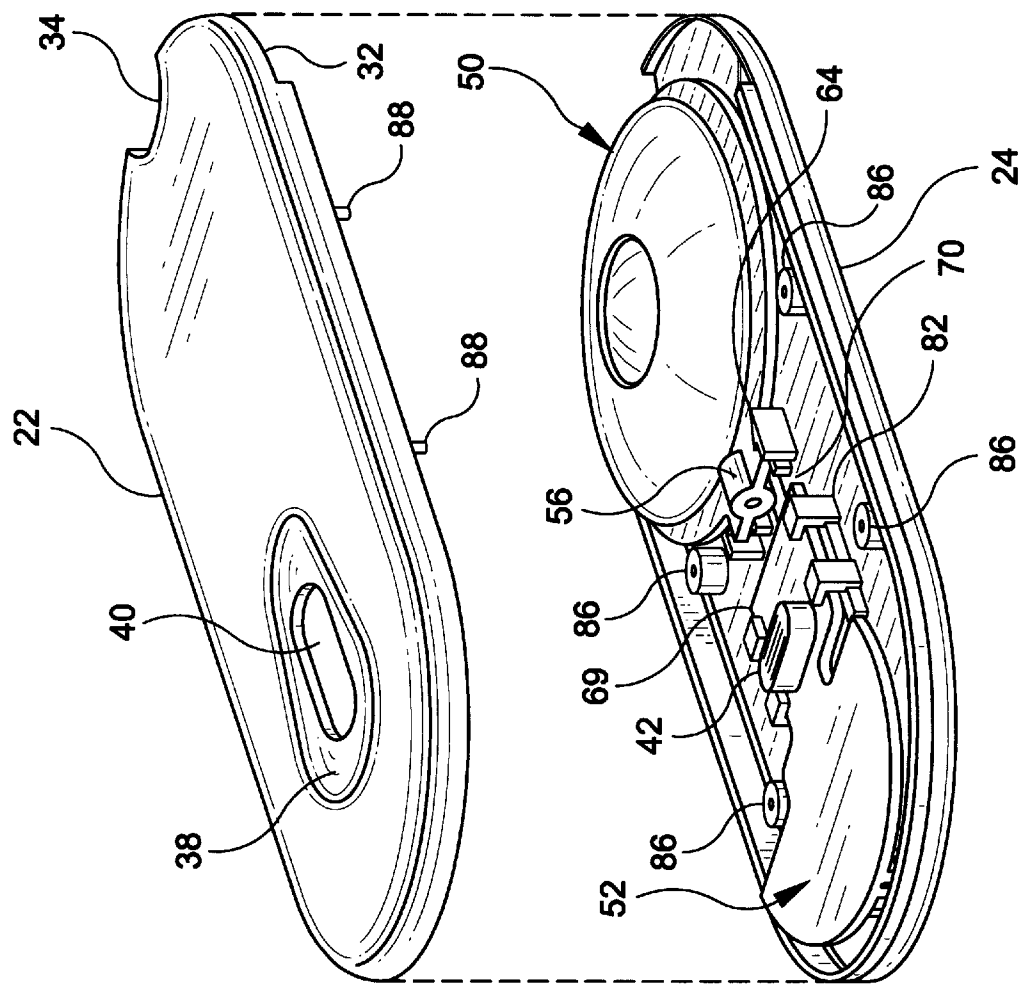
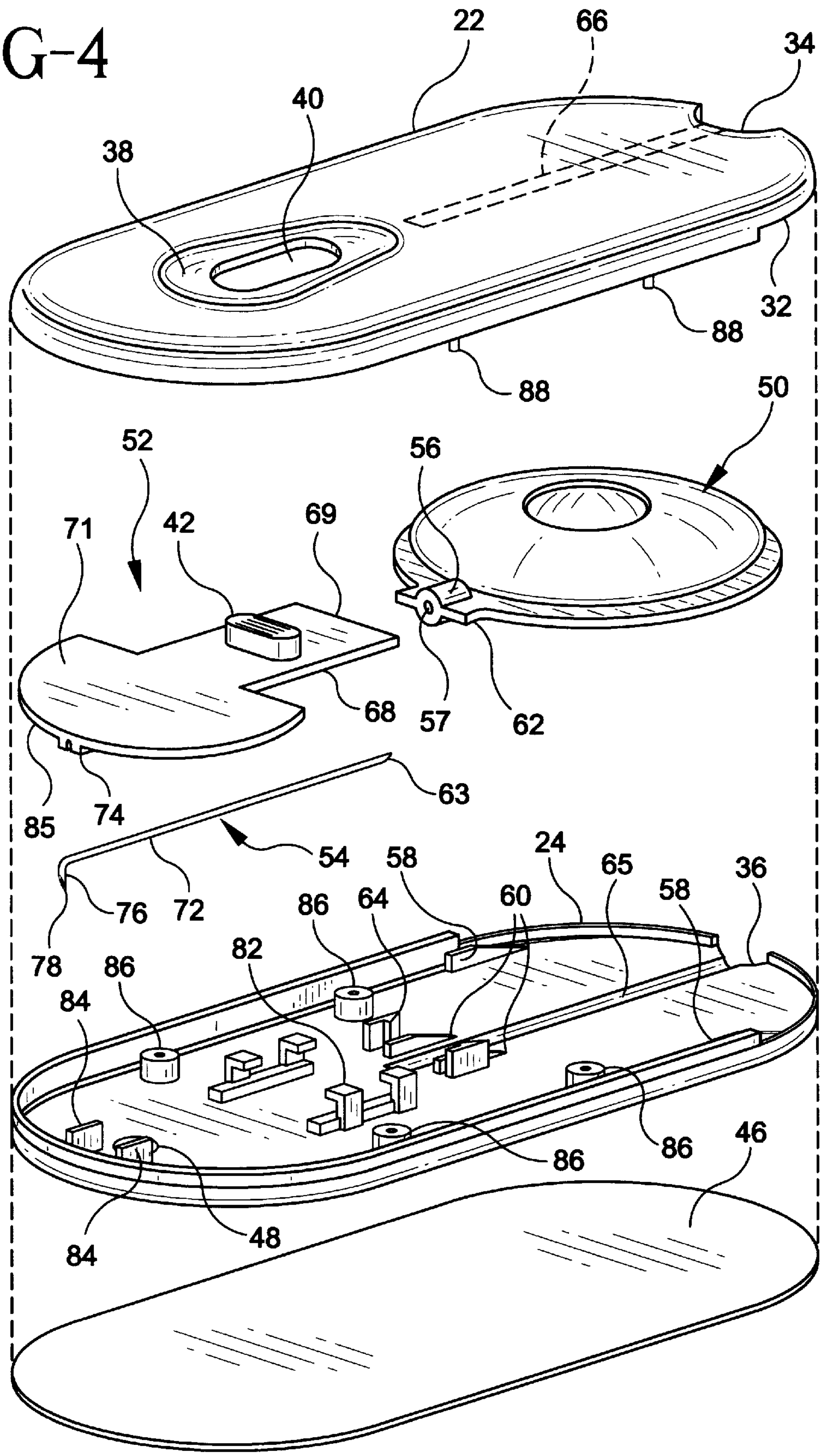


FIG-3

FIG-4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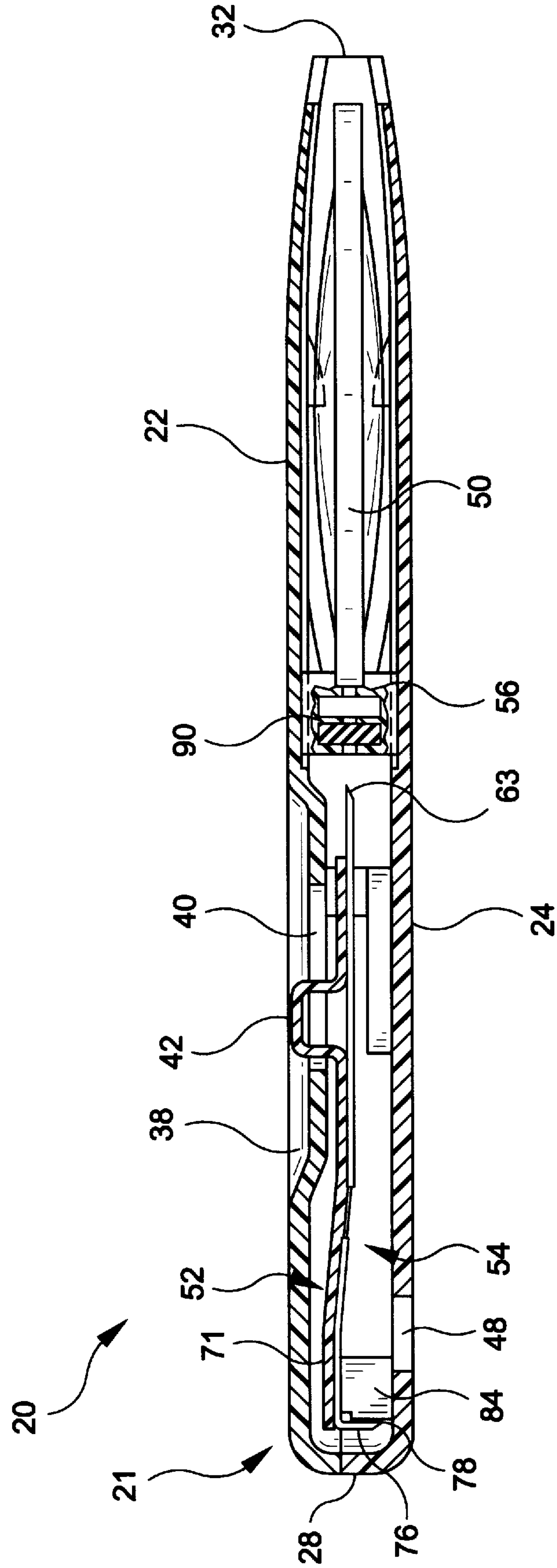


FIG-5

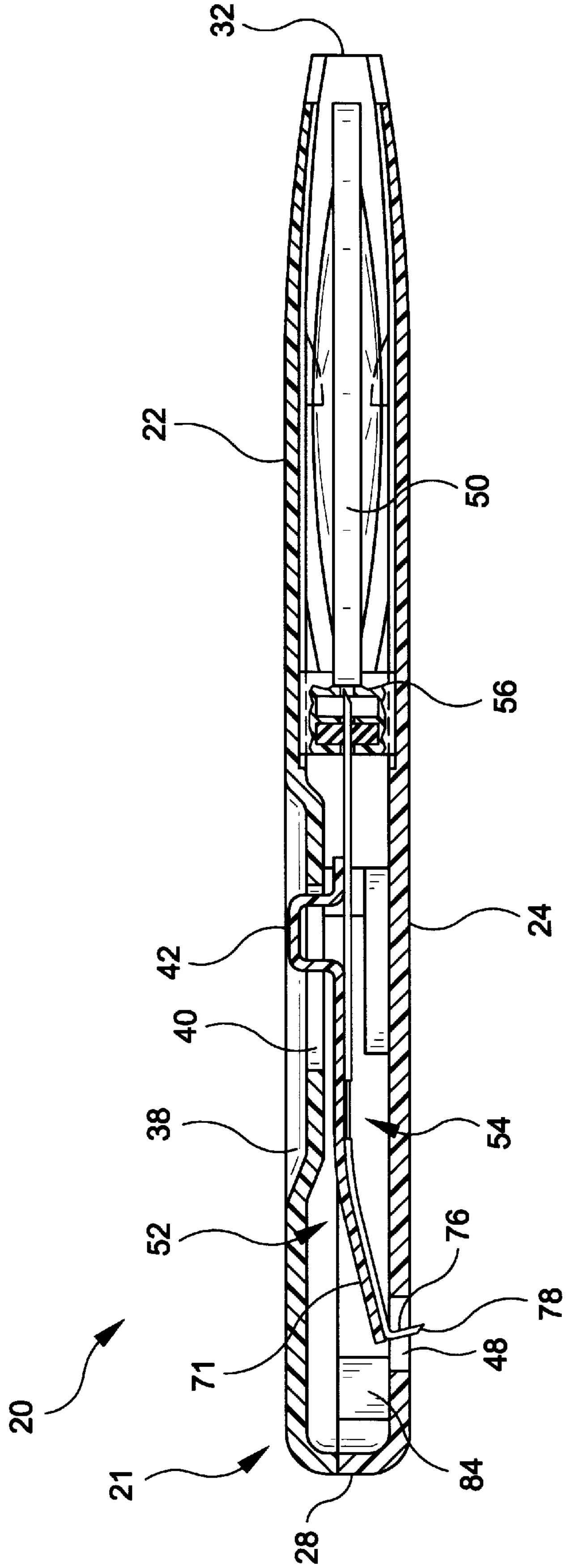
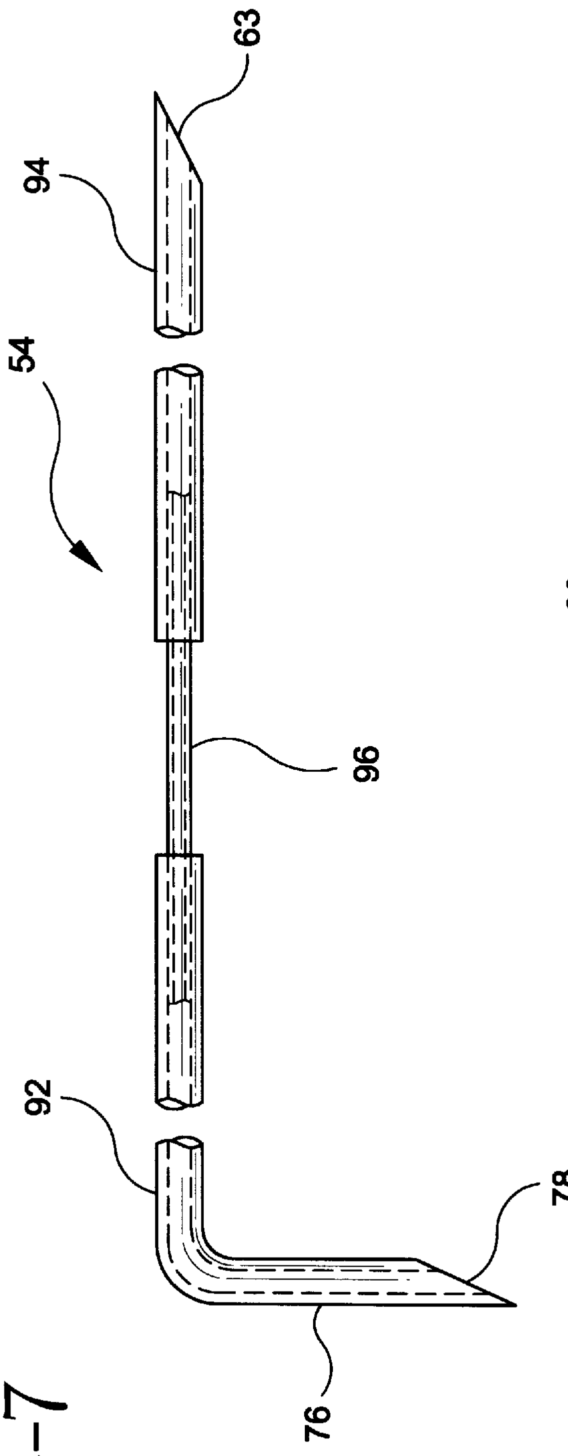


FIG-6



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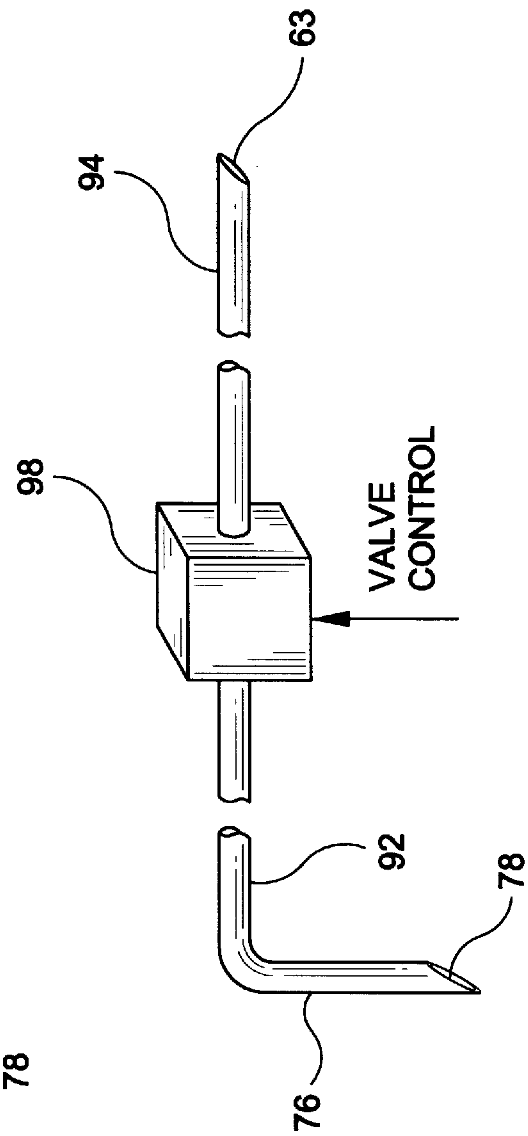

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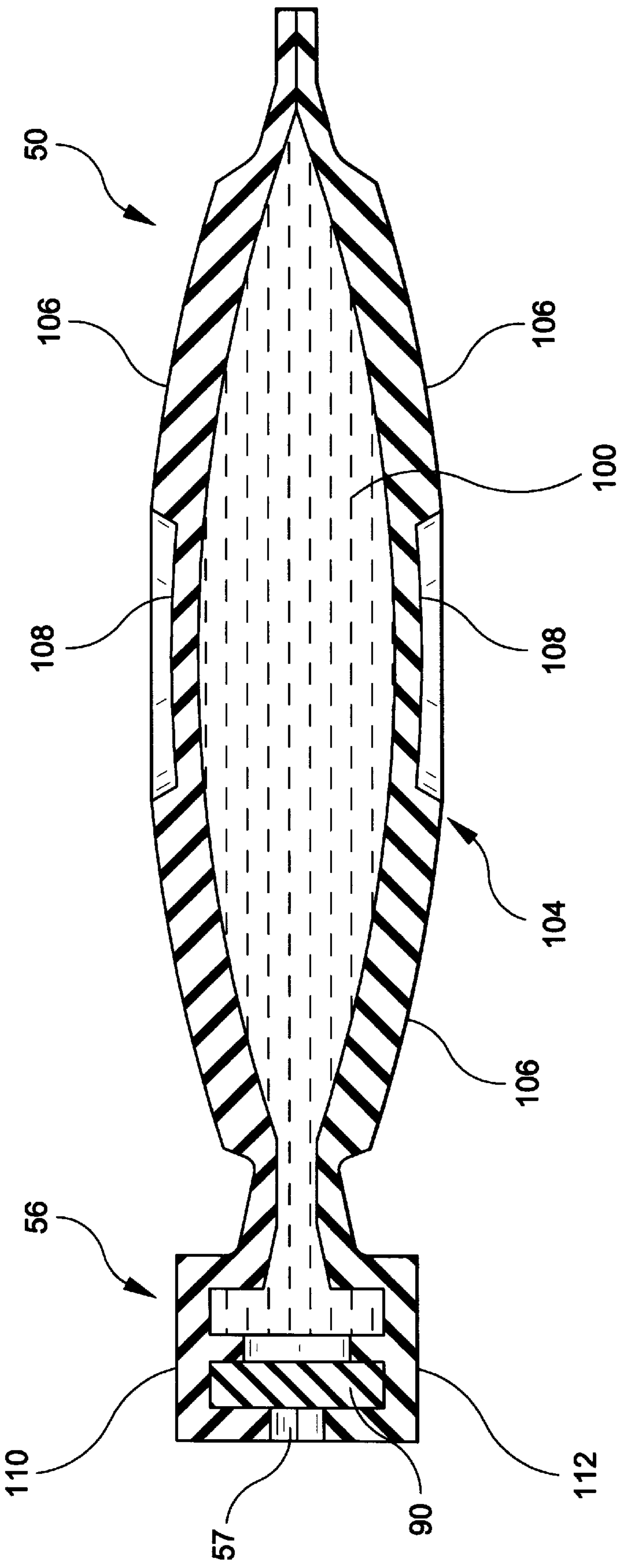

FIG-9

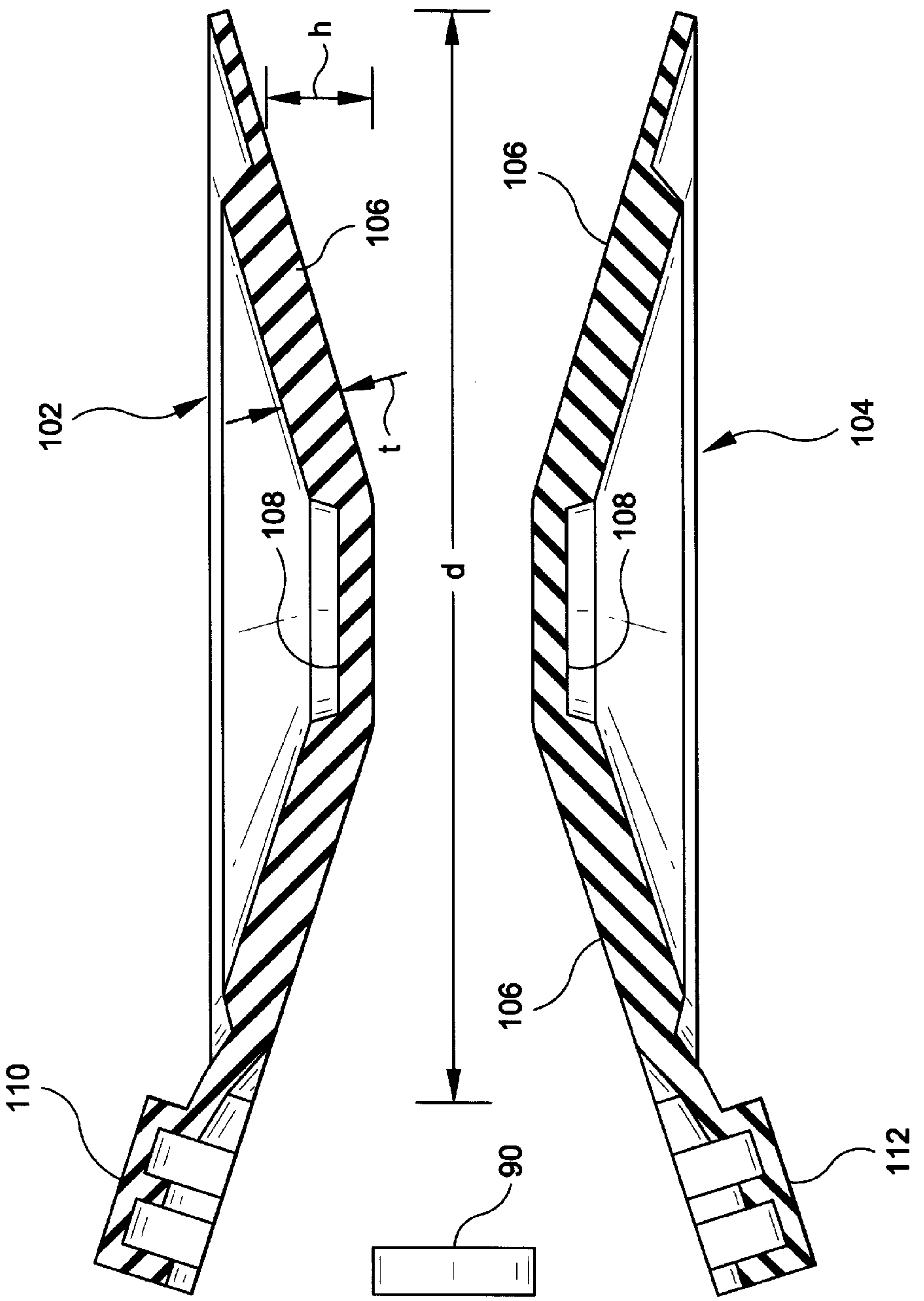

FIG-10

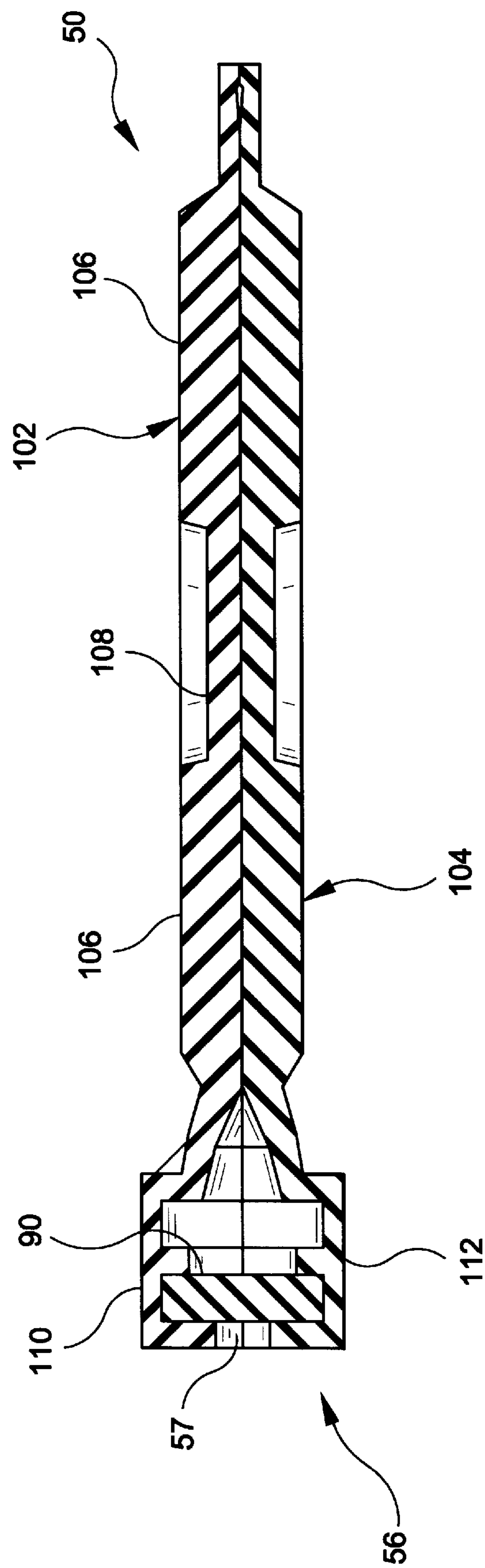

FIG-11

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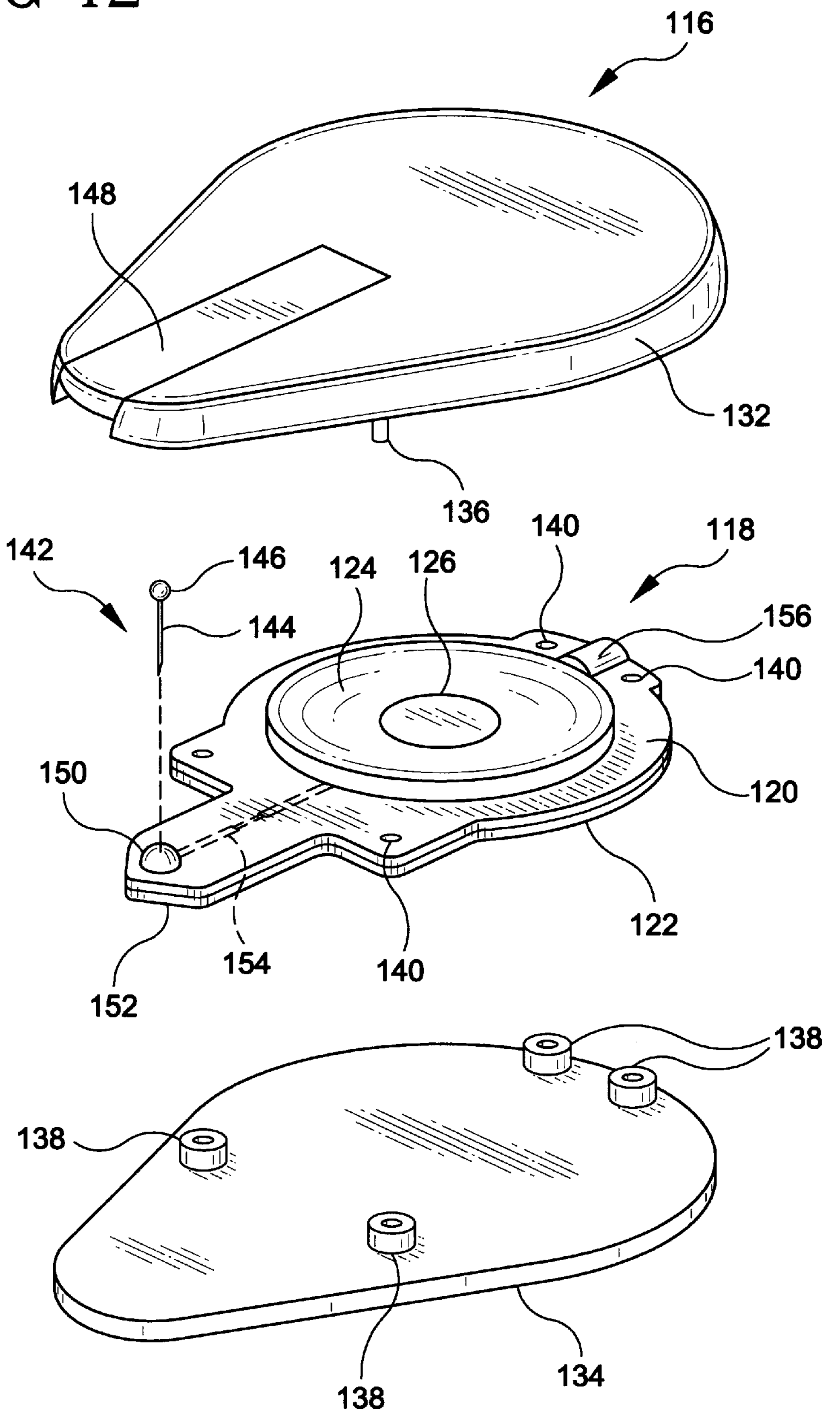
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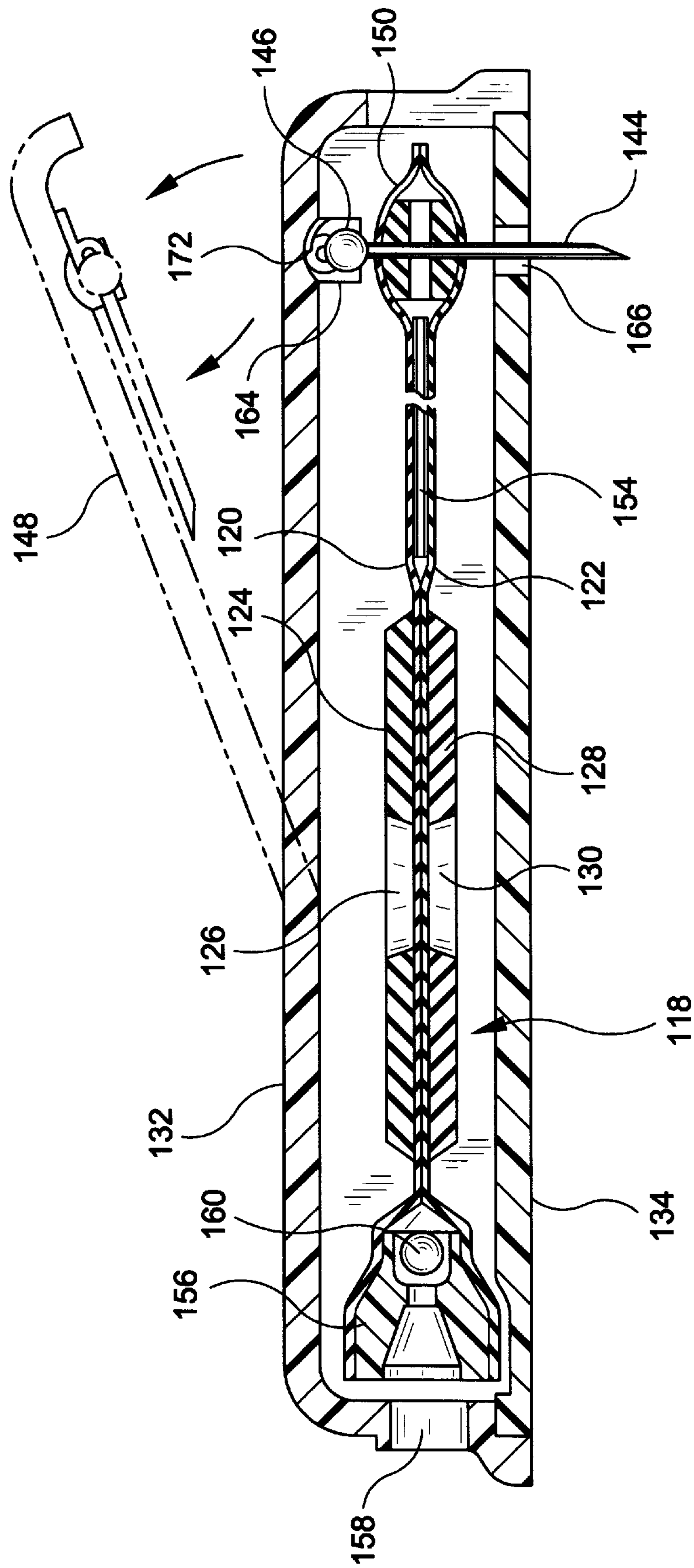
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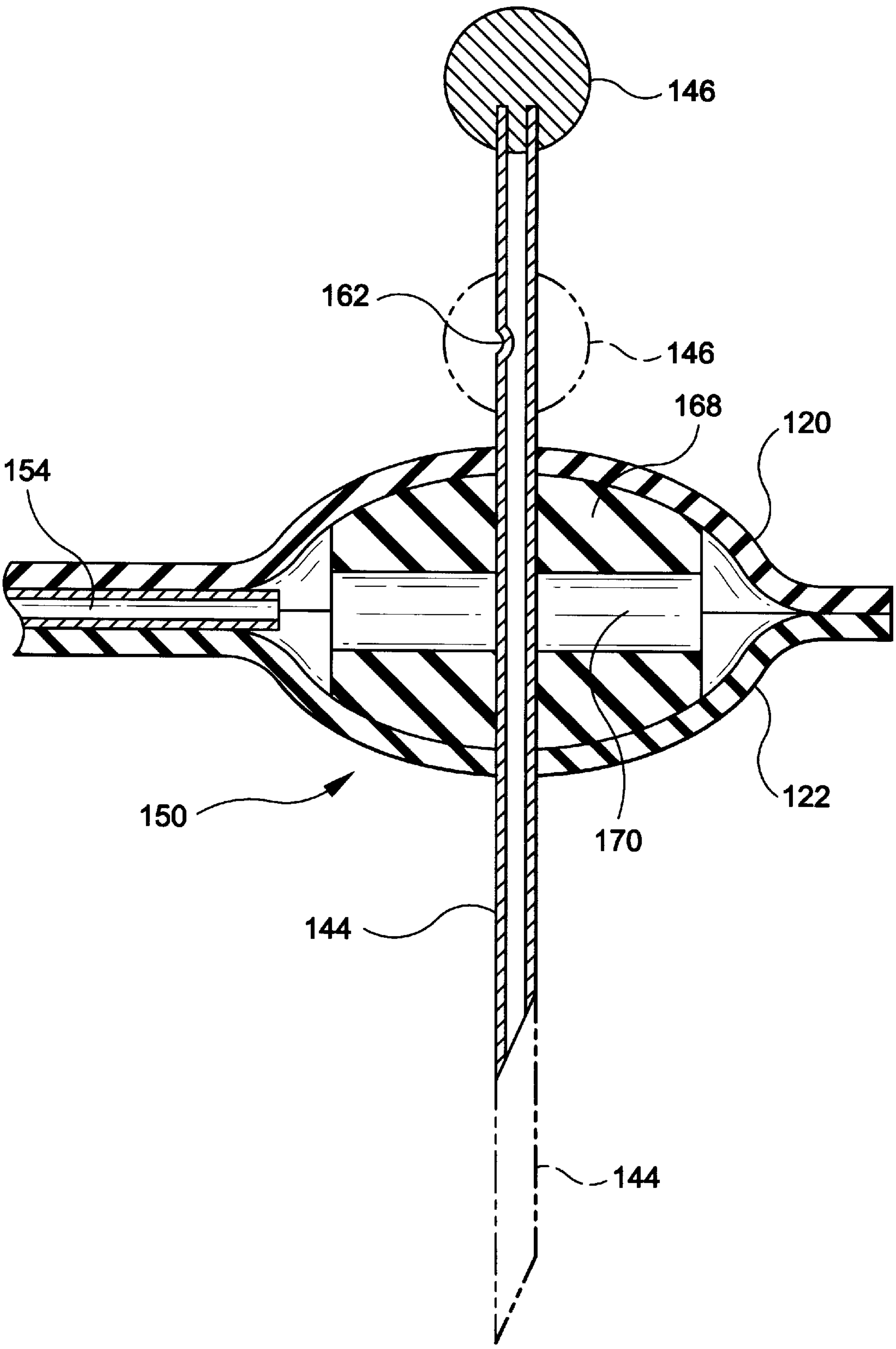
FIG-13

FIG-14



LOW-PROFILE AUTOMATIC INJECTION DEVICE WITH SELF-EMPTYING RESERVOIR

BACKGROUND OF THE INVENTION

The present invention relates generally to a device for delivering a liquid theraputic preparation into the body of a patient by injection into or though the patient's skin. More particularly, the invention relates to a low-profile automatic injection device that can be worn inconspicuously under the clothing of a patient to allow a liquid theraputic preparation (such as insulin) to be administered over an extended period of time, and that incorporates a self-emptying reservoir to eliminate the need for a pump or other type of discharge device.

Various types of automatic injection devices have been developed to allow drug solutions and other liquid theraputic preparations to be administered by untrained personnel. Generally, these devices include a reservoir that is pre-filled with the liquid theraputic preparation, and some type of automatic needle-diving mechanism (usually of the spring-loaded type) that can be triggered by the user. Examples of such devices may be found in U.S. Pat. Nos. 4,188,950, 4,196,732, 4,258,713, 4,227,528 and 4,378,015, all to Stephen C. Wardlaw. Still further examples can be found in U.S. Pat. No. 4,214,584 to Smirnov et al., U.S. Pat. Nos. 4,894,054 and 5,527,287, both to Miskinyar, and U.S. Pat. No. 5,616,132, to Newman.

In order to start the flow of the liquid theraputic preparation when the needle is injected, the devices disclosed in the aforementioned patents generally employ movable ampoules, pistons or other complex arrangements which are somewhat difficult to manufacture. Moreover, the design of these devices generally requires that the reservoir be positioned above the needle driving mechanism, which results in a device of considerable height. This is not necessarily a problem when the drug solution is to be injected as a bolus at one discrete time, as most of these devices are designed to do), but it is a distinct disadvantage when the drug solution is to be infused into the patient over an extended period of time. In these latter instances, the injection device may have to be held in contact with the patient's skin (e.g., by tape or an adhesive) for several hours or more, and this is difficult to achieve when the device has a large height dimension.

Another class of devices includes those which are capable of gradually infusing a liquid theraputic preparation into the skin of a patient. In some cases, these devices are small enough (both in height and in overall size) to allow them to be "worn" by an ambulatory patient while the liquid theraputic preparation is being infused into the patient. Examples of devices which fall in to this class include those disclosed in U.S. Pat. Nos. 4,340,048 and 4,753,651, both to Eckenhoff, U.S. Pat. No. 4,734,092, to Millerd, U.S. Pat. No. 4,781,688, to Thoma et al., U.S. Pat. No. 4,886,499, to Cirelli et al., U.S. Pat. No. 5,656,032, to Kriesel et al., and PCT Publication Nos. WO 95/13838 and WO 97/21457, both to Elan Medical Technologies, Ltd.

Unfortunately, most of the automatic infusion devices disclosed in the prior art are fairly complex in design and, as a result, cannot be made as small and inexpensive as might be desired. Generally, the complexity of these devices results from three factors. One factor is the need for a pump or other type of discharge mechanism to force the liquid theraputic preparation to flow out of the reservoir and into the injection or infusion needle. Another factor is the need

for some type of valve or flow control mechanism to cause the liquid theraputic preparation to begin to flow at the proper time. A third factor, which applies to those devices that are designed to inject the infusion needle into the patient automatically, is the need for a suitable injection mechanism that can be triggered by the user. The structures required to perform these functions add size and complexity to the infusion device, making it larger than desired and relatively expensive to manufacture.

Accordingly, a need exists for an automatic injection device that is small and has a low-profile configuration, allowing it to be conveniently handled and worn (preferably in an inconspicuous manner under the clothing) by an ambulatory patient. A need also exists for an automatic injection device which is capable of infusing a drug solution or other liquid theraputic preparation into the skin of a patient over an extended period of time. Finally, a need exists for an automatic injection device whose basic design allows it to be not only small and low in height, but also simple and inexpensive to manufacture.

SUMMARY OF THE INVENTION

In accordance with one aspect of the present invention, a device is provided for delivering a liquid theraputic preparation into the body of a patient by injection into or through the skin of the patient. The device comprises a housing having a bottom surface adapted to be brought into contact with the skin of a patient, with the bottom surface of the housing having a needle aperture therein. A reservoir is disposed within the housing for containing a liquid theraputic preparation to be administered to the patient. A needle carrier is also disposed within the housing and is movable between first and second positions within the housing, such movement occurring in a horizontal direction that is generally parallel to the bottom surface of the housing. An injection needle is carried by the needle carrier for movement therewith. The injection needle has a first portion extending generally perpendicular to the bottom surface of the housing for penetrating the skin of the patient, and a second portion extending generally parallel to the bottom surface of the housing for communicating with the reservoir. In the first position of the needle carrier, the first portion of the injection needle is retracted within the housing and the second portion of the injection needle does not communicate with the reservoir. In the second position of the needle carrier, the first portion of the injection needle projects through the needle aperture and the second portion of the injection needle communicates with the reservoir. In this way, movement of the needle carrier between the first and second positions causes the injection needle to penetrate the skin of the patient, and also causes the liquid theraputic preparation to begin to flow through the injection needle into the body of the patient.

In accordance with a further aspect of the present invention, a device for delivering a liquid theraputic preparation into the body of a patient by injection into or through the skin of the patient comprises a low-profile housing having a bottom surface adapted to be brought into contact with the skin of the patient. The bottom surface of the housing has a needle aperture therein, and the housing is sufficiently low in height to allow the device to be worn inconspicuously under the clothing of the patient. A reservoir is disposed within the housing for containing a liquid theraputic preparation to be administered. An injection needle is disposed generally horizontally in the housing, and is adapted to communicate with the reservoir. The injection needle has a bent injection end which is adapted to project

through the needle aperture. A movable needle carrier is disposed in the housing for carrying the injection needle and for causing the injection end of the needle to project through the needle aperture upon movement of the needle carrier. The needle carrier and the injection needle are disposed in a side-by-side relationship with the reservoir in the housing in order to minimize the height of the housing above the bottom surface.

In accordance with a still further aspect of the present invention, a device for delivering a liquid theraputic preparation into the body of a patient by injection into or through the skin of the patient comprises a housing adapted to be held in contact with the patient's skin. A reservoir is disposed within the housing for containing a liquid theraputic preparation to be administered. The reservoir includes a Belleville spring which exerts pressure on the liquid theraputic preparation to discharge the liquid theraputic preparation from the reservoir at a relatively constant rate. An injection needle is adapted to communicate with the reservoir and to project from the housing in order to inject the liquid theraputic preparation into or through the skin of the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

The various objects, advantages and novel features of the present invention will be more readily appreciated from the following detailed description when read in conjunction with the appended drawings, in which:

FIG. **1** is a top perspective view of an automatic injection device constructed in accordance with a first embodiment of the present invention;

FIG. **2** is a bottom perspective view of the automatic injection device of FIG. **1**, illustrating the needle aperture and peelable release liner thereof;

FIG. **3** is a partially exploded perspective view of the automatic injection device of FIGS. **1** and **2**, with the top portion of the housing removed and the internal components of the device shown in their operative positions in the bottom portion of the housing;

FIG. **4** is a fully exploded perspective view of the automatic injection device of FIGS. **1–3**, with the internal components of the device shown removed from the bottom portion of the housing;

FIG. **5** is a cross-sectional view taken along the line **5—5** in FIG. **1**, illustrating the components of the automatic injection device in the positions they occupy prior to use of the device;

FIG. **6** is a cross-sectional view similar to that of FIG. **5**, illustrating the components of the automatic injection device in the positions they occupy during and after use;

FIG. **7** is an enlarged side view of the injection needle used in the device of FIGS. **1–6**, showing the capillary tube that is used for flow rate control;

FIG. **8** is a side view of an alternative embodiment of the injection needle in which a valve is used for flow rate control;

FIG. **9** is a cross-sectional view of the liquid reservoir or dose chamber used in the device of FIGS. **1–8**, with the liquid theraputic preparation present within the reservoir;

FIGS. **10** and **11** illustrate the components of the liquid reservoir of FIG. **8** and the manner in which they are assembled;

FIG. **12** is an exploded perspective view of an automatic injection device constructed in accordance with a second embodiment of the present invention;

FIG. **13** is a cross-sectional view of the automatic injection device of FIG. **12**, shown fully assembled; and

FIG. **14** is an enlarged view of a portion of FIG. **13**, illustrating the manner in which the flow of the drug solution to the injection needle is controlled.

Throughout the drawings, like reference numerals will be understood to refer to like parts and components.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

An automatic injection device **20** constructed in accordance with a first embodiment of the present invention is illustrated generally in the top and bottom perspective views of FIGS. **1** and **2**, respectively. The device **20** includes a rigid external housing **21** that consists of an upper housing portion **22** and a lower housing portion **24**. The housing portions **22** and **24** may be made of a suitable plastic material, such as polycarbonate, and are joined to each other along a horizontal seam **26**. The plastic material used for the housing **21** is preferably opaque, but may be transparent or translucent if desired. When viewed from above or below, the housing **21** has an oblong shape with rounded ends, as shown. The forward end **28** of the housing **21** is closed, but the rear end **30** of the housing includes a horizontally-extending slot **32** (formed by a notch in the upper housing portion **22**) which allows access to the interior of the housing. The slot **32** allows a pre-filled liquid reservoir or dose chamber to be installed in the housing **21** after the device **20** has been assembled. Horizontal, crescent-shaped cut-outs **34** and **36** are formed in the upper and lower portions **22** and **24** of the housing **21** at the rear end **30** thereof to allow the liquid reservoir to be fully inserted.

As shown in FIG. **1**, the upper portion **22** of the housing is formed with a recessed area **38** in which a hole **40** is formed. The hole **40** is elongated in the lengthwise direction of the device **20**, and accommodates a slide button **42** which is operated by the user. The top surface of the slide button **42** is ribbed in a direction perpendicular to the direction of button movement, as shown, to allow the user's finger to engage the button **42** without slipping. The button **42** is initially in the position shown in FIG. **1** and is moved rearwardly (i.e., in the direction toward the rear end **30** of the housing **21**) by the user during operation of the device **20**. As will be described in detail below, movement of the button **42** causes an injection needle to project from the bottom of the housing **21** and also causes the liquid theraputic preparation to begin to flow through the injection needle from the internal reservoir.

As shown in FIG. **2**, the bottom surface of the housing is flat and carries a layer of pressure-sensitive adhesive **44** which allows the device **20** to be affixed to the skin of a patient. The tackiness of the adhesive layer **44** is sufficient to allow the device **20** to remain securely attached to the patient's body, but is weak enough to allow the device **20** to be removed from the skin after use without discomfort. A suitable adhesive which may be used for this purpose is available from **3M** Company of St. Paul, Minn. Preferably, the bottom surface of the housing **21** is roughened or textured to allow for better adhesion of the pressure-sensitive adhesive layer **44** to the plastic material of the housing. A release liner **46**, made of coated paper or a thin sheet of plastic, covers the adhesive layer **44** prior to use of the device **20**. When the release liner **46** is removed, it uncovers not only the adhesive layer **44** but also a small round hole **48** that is formed through the bottom portion **24** of the housing near its forward end **28**. The hole **48** serves

as a needle aperture for allowing an injection needle to protrude from the bottom of the device **20** when the slide button **42** of FIG. **1** is actuated, as will be described in detail below.

In the preferred embodiment, the automatic injection device **20** of FIGS. **1** and **2** is approximately 3.6 inches in length, approximately 1.8 inches in width and approximately 0.4 inch or less in height. However, these dimensions are given merely by way of example and not by way of limitation, it being understood that both the dimensions of the device **20** and its overall shape or geometry may be varied nm order to suit the requirements of particular applications.

FIGS. **3** and **4** are exploded views which illustrate the internal components of the automatic injection device **20**. These components include a liquid reservoir or dose chamber **50**, a needle carrier **52** and an injection needle **54**. The liquid reservoir **50**, whose detailed construction will be discussed below in connection with FIGS. **9–11**, is preferably in the form of a thin disk-shaped structure as shown. A cylindrical fill and discharge port **56** is formed on the side of the reservoir **50** and faces the rear edge **69** of the needle carrier **52**. The liquid reservoir **50** is made of a suitable plastic material, such as ABS plastic, and defines a thin, disk-shaped internal chamber in which a liquid theraputic preparation (such as insulin) is stored. The circular aperture **57** of the port **56** is closed off by an internal, self-sealing rubber septum (not visible in FIGS. **3** and **4**) which maintains the reservoir **50** in a sealed condition until it is penetrated by the injection needle **54** during use of the device **20**. Preferably, the reservoir **50** is pre-filled with the liquid theraputic preparation (via needle injection through the port **56**) and is inserted into the automatic injection device **20** through the slot **32** after the device **20** has been assembled. When the reservoir **50** is inserted into the slot **32**, a pair of upstanding ramps **58** which are integrally formed on the bottom portion **28** of the housing assist in locating the reservoir **50** at the proper height within the housing. A similar pair of ramps **60**, spaced more closely together and located closer to the forward end **28** of the housing than the ramps **58**, engage a pair of horizontal wings or tabs **62** which extend from either side of the port **56**. As a result, the circular aperture **57** at the center of the port **56** is aligned precisely with the rearwardly-facing end **63** of the injection needle **54**. When the reservoir **50** reaches the proper position within the housing **21**, the rear edges of the wings **62** are captured between a pair of upstanding detents **64** which, like the ramps **58** and **60**, are formed integrally with the bottom portion **24** of the housing **21**. The detents **64** serve to lock the reservoir **50** in position within the housing **21** of the automatic injection device **20**. The reservoir **50** is guided into engagement with the detents **64** by a shallow channel **65** which receives the lowermost edge of the port **56** and extends longitudinally along the interior surface of the bottom housing portion **24**. A similar channel **66** extends longitudinally along the interior surface of the upper housing portion **22** to receive and guide the uppermost edge of the port **56**.

With continued reference to FIGS. **3** and **4**, the needle carrier **52** is received in the lower portion **24** of the housing in a side-by-side relationship with the reservoir **50**. The needle carrier **52** is made of a strip of resilient plastic material, such as 0.040 inch thick ABS plastic. The needle carrier **52** includes a generally rectangular guide portion **68** on which the slide button **42** is integrally formed. The rear edge **69** of the guide portion **68** faces the reservoir **50**, and is separated from the port **56** of the reservoir by a small gap

70 as shown in FIG. **3**. Integral with the guide portion **68** of the needle carrier **52** is a resiliently deflectable portion **71** which, when viewed from above, has an arcuate or curved shape corresponding generally to the shape of the forward portion **28** of the housing. As best seen in FIG. **4**, the resiliently deflectable portion **71** of the needle carrier **52** is angled downwardly (preferably by about 7°) from the plane of the guide portion **68** when the deflectable portion **71** is in its relaxed or unstressed condition. The injection needle **54** is secured to the bottom surface of the needle carrier **52** in a manner such that the main or unbent portion **72** of the injection needle **54** extends approximately parallel to the plane of the lower housing portion **24** and is aligned with the longitudinal center line of the device **20**. The injection needle **54** may be affixed to the lower surface of the needle carrier **52** in any desired manner, but the preferred method is to capture portions of the injection needle **54** between projections (two of which are visible at **74** in FIG. **4**) extending from the lower surface of the needle carrier **52**. An expoy resin may also be used to secure the injection needle **54** in place. The forward or distal end **76** of the injection needle **54** is bent at an angle of about 90° relative to the main or proximal portion **72** of the injection needle, and penetrates the skin of the patient during operation of the device **20**. As described below in connection with FIGS. **7** and **8**, the injection needle **54** is preferably made up of two connected sections of hollow 30-gauge stainless steel cannula, with each section ground at an angle at its free end to provide a sharpened distal end **78** and a sharpened proximal end **63**. The 90° bend which separates the distal portion **76** of the injection needle **54** from the main or proximal portion **72** is preferably in the form of a smooth arc, as shown, in order to avoid any obstruction in the flow of the liquid theraputic preparation through the injection needle **54**.

Unlike the liquid reservoir **50**, which is held at a fixed position within the housing **21**, the needle carrier **52** is slidable relative to the lower portion **24** of the housing. This is achieved by means of a pair of upstanding guide track structures **82** which are formed integrally with the lower portion **24** of the housing. As best seen in FIG. **3**, the rectangular guide portion **68** of the needle carrier **52** is slidably received between the guide tracks **82** so that it can move longitudinally (i.e., in the direction toward the liquid reservoir **50**) when the slide button **42** is manipulated by the user. This provides a corresponding motion of the injection needle **54**, which is affixed to the bottom of the needle carrier **52** as described previously. During movement of the needle carrier **52**, the upper and lower horizontal portions of the guide tracks **82** restrain vertical movement of the guide portion **68**. When the needle carrier **52** is at its forwardmost position in the lower housing portion **24**, the front edge **85** of the resiliently deflectable portion **71** is deflected upwardly from its relaxed or unstressed configuration by a pair of upstanding rectangular supports or projections **84** which are formed integrally with the bottom portion **24** of the housing near its forward end **28**. Since the guide portion **68** at the rear of the needle carrier **52** is prevented from moving upwardly by the guide tracks **82**, the needle carrier **52** is thus maintained in a resiliently stressed condition with the forward edge of the resiliently deflectable portion **70** bearing downwardly on the supports **84**. This is the condition in which the needle carrier **52** exists prior to use of the automatic injection device **20**. When the device **20** is used, the needle carrier **52** is moved (via the slide button **42**) in the direction toward the reservoir **50**, thereby removing the forward edge **85** of the resiliently deflectable portion **70** from contact with the supports **84**. This allows the resiliently deflectable portion

70 of the needle carrier 52 to deflect downwardly under its own inherent spring force. This motion provides the injection force that causes the distal portion 76 of the injection needle 54 to penetrate the skin of the patient.

As shown in FIGS. 3 and 4, upstanding cylindrical sockets 86 are integrally formed on the interior surface of the lower housing portion 24. These sockets 86 mate with corresponding pins or studs 88 which are formed integrally with the interior surface of the upper housing portion 22 and which extend downwardly toward the lower housing portion. Tight engagement between the pins 88 and sockets 86 serves to couple the upper and lower housing portions 22 and 24 together during assembly of the automatic injection device 20.

FIGS. 5 and 6 are cross-sectional views which illustrate the manner in which the automatic injection device 20 is used. FIG. 5 illustrates the device 20 as it would appear prior to use, with the slide button 42 in its forwardmost position and the distal tip 78 of the injection needle 54 recessed within the forward end 28 of the housing 21. The release liner 46 has been removed from the bottom of the housing 21 in FIG. 5, and the bottom surface of the housing has been placed against the skin of the patient (not shown) so that the needle aperture 48 is directly over the desired injection site. When the slide button 42 is moved rearwardly in the hole 40 (i.e., in the direction toward the reservoir 50), the forward edge 85 of the deflectable portion 71 of the needle carrier 52 is withdrawn from the supports 84, allowing the deflectable portion 71 to resiliently return to its relaxed or unstressed condition as shown in FIG. 6. When this occurs, the bent portion 76 of the injection needle 54 projects downwardly through the needle aperture 48 and the sharpened distal tip 78 of the injection needle penetrates the skin of the patient. The depth of penetration is preferably about 3 millimeters or less. At the same time, the rearward movement of the needle carrier 52 causes the sharpened tip 63 at the proximal end of the injection needle 54 to penetrate a self-sealing rubber septum 90 in the port 56 of the liquid reservoir 50. The proximal end of the injection needle 54 thereby enters the liquid chamber within the reservoir 50, as shown in FIG. 6, and a flow path is established between the reservoir 50 and the body of the patient through the lumen of the injection needle 54. It will be appreciated that contact between the port 56 and the read edge 69 of the needle carrier 52 will act as a stop for the rearward motion of the injection needle 54, thereby limiting the depth of penetration of the injection needle 54 into the reservoir 50. As will be discussed in connection with FIGS. 7 and 8, the rate of liquid flow through the injection needle 54 is controlled so that the liquid theraputic preparation is discharged from the reservoir 50 gradually over a predetermined interval. In the case where the liquid theraputic preparation is insulin, for example, this period of time may be approximately twenty-four hours. As will become apparent from the discussion of FIGS. 9–11 below, the inherent resiliency of the walls of the liquid reservoir 50 allows the liquid theraputic preparation to be discharged from the reservoir 50 without the need for a pump or other type of discharge device.

FIG. 7 illustrates a preferred type of injection needle 54 which may be employed in the present invention. The injection needle 54 is made up of two sections 92 and 94, each consisting of a length of 30-gauge stainless steel cannula A glass capillary tube is tightly received in the lumens of the cannula sections 92 and 94 and serves to couple them together. The length and inner diameter of the glass capillary tube 96 provides a fixed, calibrated flow resistance that establishes the rate of liquid flow through the injection needle 54. In the preferred embodiment, the glass capillary tube 96 has a length of approximately 1 inch, an outer diameter of approximately 150 microns and an inner diameter of approximately 29 microns. The epoxy resin that is used to attach the injection needle 54 to the needle carrier 52 may also be used to secure the connection between the glass capillary tube 96 and the stainless steel cannula sections 92 and 94.

FIG. 8 illustrates a modified embodiment in which the cannula sections 92 and 94 are coupled by a valve 98 rather than by the glass capillary tube 96. When the valve 98 is closed, the liquid theraputic preparation is prevented from flowing through the injection needle 54. When the valve 98 is opened, the liquid theraputic preparation can flow through the injection needle 54 and into the body of the patient. The size of the valve orifice controls the rate of liquid flow through the injection needle 54. The valve 98 may be controlled either mechanically or electrically. In either case, the valve control can be interconnected with the slide button 42 or provided as a separate control on the exterior of the housing 21. Optionally, a proportional valve may be used so that the rate of liquid flow through the injection needle 54 can be varied to suit the requirements of particular patients and/or liquid theraputic preparations.

FIGS. 9–11 illustrate the details of the liquid reservoir 50. In FIG. 9, the reservoir 50 is shown in its assembled condition and is filled with a liquid theraputic preparation 100. The body of the reservoir 50 consists of two circular Belleville spring diaphragms 102 and 104 which are bonded to each other at their edges. Each Belleville spring diaphragm is about 1.70 inches in diameter and is made of a suitable resilient plastic material, such as ABS or polycarbonate. Each Belleville spring diaphragm 102 and 104 includes an outer annular portion 106 which has a thickness of about 0.030 inch, and a thinner central disk portion which has a thickness of about 0.020 inch. Semi-cylindrical structures 110 and 112 extend from one side of each Belleville spring diaphragm 102 and 104 to form the port 56. A self-sealing cylindrical rubber septum 90 is captured within a correspondingly-shaped cavity in the port 56 to seal the aperture 57, which serves as the inlet and outlet of the reservoir 50. In the empty condition of the reservoir 50, the inner surfaces of the Belleville spring diaphragms 102 and 104 are in contact with each other as shown in FIG. 11. The liquid theraputic preparation 100 is injected under pressure by a filling needle through the rubber septum 90, and this causes the Belleville spring diaphragms 102 and 104 to forcibly separate as shown in FIG. 9. When the filling needle is removed, the rubber septum 90 self-seals and maintains the liquid theraputic preparation 100 in a pressurized condition within the reservoir 50.

FIG. 10 illustrates the configuration of the Belleville spring diaphragms 102 and 104 before the reservoir 50 is assembled. As illustrated, each Belleville spring diaphragm 102 and 104 has the shape of a truncated cone, with the apexes of the two truncated cones facing each other. During the assembly process, the outer edges of the two Belleville spring diaphragms 102 and 104 are forced together and are secured to each other by ultrasonic welding. The ultrasonic welding process bonds the edges of the two Belleville spring diaphragms 102 and 104 together at all points along their peripheries, except for a gap in the region of the port 56. The gap provides a liquid channel which communicates with the septum 90 and aperture 57. After the ultrasonic bonding operation is complete, the reservoir 50 has the configuration shown in FIG. 11. As noted earlier, introduction of the liquid theraputic preparation 100 under pressure through the sep-

tum **90** causes the Belleville spring diaphragms **102** and **104** to separate, leaving the reservoir in the condition shown in FIG. **9**. The resiliency of the Belleville spring diaphragms **102** and **104** (which tends to return them to the configuration shown in FIG. **10**) maintains the liquid theraputic preparation **100** under pressure. When the injection needle **54** of the automatic injection device **20** penetrates the septum **90**, the pressure exerted by the Belleville spring diaphragms **102** and **104** causes the liquid theraputic preparation **100** to be discharged through the injection needle **54** without the need for a pump or other type of discharge device.

One of the advantages of the reservoir construction shown in FIGS. **9–11** is that the Belleville spring diaphragms **102** and **104** exert a relatively constant pressure on the liquid theraputic preparation **100** that is essentially independent of the amount of liquid remaining within the reservoir **50**. This produces a relatively constant flow rate of the liquid theraputic preparation **100** through the injection needle **54**, which allows the liquid theraputic preparation **100** to be administered to the patient at a constant infusion rate. In order to achieve this result, a specific geometry is preferably used for each of the Belleville spring diaphragms **102** and **104**. In particular, it has been found that the ratio between the vertical height projection of the thicker annular region **106** of each Belleville spring diaphragm (the dimension "h" in FIG. **10**) and the thickness of this region (the dimension "t" in FIG. **10**) should be in the range of about 1.7 to about 2.0. For a Belleville spring diaphragm having an effective diameter (the dimension "d" in FIG. **10**) of about 1.70 inches, the dimension "h" preferably has a value of about 0.060 inch and the dimension "t" preferably has a value of about 0.030 inch. When the reservoir **50** is completely filled with the liquid theraputic preparation as shown in FIG. **9**, the interior height dimension at the center of the reservoir is about 0.060 inch.

FIG. **12** is an exploded perspective view of an automatic injection device **116** constructed in accordance with a second embodiment of the present invention. In this embodiment, the liquid reservoir **118** comprises two flexible membranes **120** and **122**, made of rubber or plastic, which are bonded together at their outer edges. A Belleville washer **124** with a hollow center **126** is bonded to the outside of the top membrane **120**, and a similar Belleville washer **128** (visible in FIG. **13**) with a hollow center **130** is bonded to the outside of the bottom membrane **122**. Except for their hollow centers **126** and **130**, the Belleville washers **124** and **128** are similar in construction and function to the Belleville spring diaphragms **102** and **104** shown in FIGS. **9–11**. In the embodiment of FIG. **12**, however, the sole function of the Belleville washers **124** and **128** is to pressurize the liquid theraputic preparation contained within the liquid reservoir **118**, but the Belleville washers **124** and **128** do not themselves form the walls of the chamber. The latter function is carried out by the bonded membranes **120** and **122**. This is advantageous in allowing the material of the Belleville washers **124** and **128** to be selected solely on the basis of its mechanical characteristics, without regard to its compatibility with the liquid theraputic preparation contained in the reservoir **118**.

With further reference to FIG. **12**, the liquid reservoir **118** is enclosed in a housing which consists of an upper portion **132** and a lower portion **134**. Pins **136** extend downwardly from the upper portion **132** of the housing and mate with sockets **138** formed in the lower portion **134** of the housing after passing through holes **140** located at the periphery of the bonded membranes **120** and **122**. This method of construction serves to couple the upper and lower housing

portions **132** and **134** together while properly locating the liquid reservoir **118** within the housing. Also visible in FIG. **12** is an injection needle **142** which communicates with the liquid reservoir **118**. The injection needle **142** consists of a straight stainless steel cannula **144** which is ground at an angle at its lower end, and is capped at its upper end by a round plastic insert **146**. Actuation of a hinged cut-out section **148** of the upper housing portion **132** by the user causes the injection needle to be displaced through a delivery node **150** formed in an extension **152** of the liquid reservoir **118**. The delivery node **150** is in fluid communication with the liquid theraputic preparation in the reservoir **118** by means of a glass capillary tube **154** which serves as a fixed flow resistor and establishes the desired flow rate of the liquid theraputic preparation through the injection needle **142**.

The manner in which the automatic injection device **116** of FIG. **13** is used will now be explained with reference to FIGS. **13** and **14**. After the device **116** is assembled, the liquid reservoir **118** is filled by inserting a suitable filling nozzle through a hole **158** formed in the upper portion **132** of the housing and coupling the suitable filling nozzle to a port **156** located on the rear portion of the reservoir **118**. A ball-type check valve **160** allows the liquid theraputic preparation to enter the reservoir **118** but prevents it from being discharged through the port **156** after the reservoir has been filled. Filling of the reservoir **118** will cause the membranes **120** and **122** and the Belleville washers **124** and **128** to forcibly separate, thereby defining a liquid chamber between the separated membranes and Belleville washers. Prior to use of the device **116**, the movable section **148** of the upper housing portion **132** is in the portion shown in solid lines in FIG. **14**. In this position, the cannula **144** of the injection needle **142** is recessed entirely within the housing, and a hole **162** formed in the side of the cannula **144** is located at a position above and outside the delivery node **150**. As shown in FIG. **13**, the plastic cap **146** at the top of the injection needle **142** is held in a socket **164** which is affixed to the bottom surface of the movable housing section **148**. To inject the needle **142**, the user depresses the movable housing section **148** until it reaches the solid line position shown in FIG. **13**. This causes the distal end of the injection needle **142** to project from a needle aperture **166** in the bottom portion **134** of the housing, and also causes the portion of the injection needle cannula containing the hole **162** to enter the delivery node **150** (as illustrated in phantom lines in FIG. **14**). When the hole **162** aligns with the center of the delivery node **150**, a liquid path exists between the interior of the reservoir **118** and the distal tip of the injection needle **142**. The liquid theraputic preparation is then automatically discharged from the reservoir **118** through the injection needle **142** in the same manner as in the previous embodiment, with the rate of discharge being established by the dimensions of the glass capillary tube **154**. An elastomeric seal **168** is provided in the delivery node **150** in order to prevent leakage of the liquid theraputic preparation at the membranes **120**, **122** and the cannula **144** of the injection needle **142**. The elastomeric seal **168** also defines a central opening **170** with which the side opening **162** in the needle cannula **144** can align, thereby insuring that the desired fluid path will exist. The opening **162** can be formed in the cannula **144** in various ways, but a technique known as electrical discharge machining (EDM) is particularly useful for this purpose.

After the liquid theraputic preparation has been completely discharged from the reservoir **118**, the automatic injection device **116** can be removed from the body of the patient in the same manner as the device **20** described

previously. At this point, the movable section **148** in the upper portion **132** of the housing can be raised to the position shown in phantom lines in FIG. **13**. When this is done, the cannula **144** is withdrawn from the delivery node **150**, and a spring **172** in the socket **164** causes the injection needle **142** to pivot to a position generally parallel to the inside surface of the movable housing section **148**. The movable housing section **148** may then be restored to its closed position, leaving the injection needle **142** fully retracted at a safe position within the housing.

It will be appreciated that the automatic injection devices **20** and **116** can be used to administer virtually any type of theraputic preparation that is in a liquid or flowable form. Examples include liquids, solutions, suspensions, flowable gels and the like. It will also be apparent that the devices **20** and **116** can be used for either intradermal, subcutaneous, intramuscular or intravenous delivery of the theraputic preparation.

Although only two exemplary embodiments of the invention have been described in detail above, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of the invention as defined in the following claims.

What is claimed is:

1. A device for delivering a liquid theraputic preparation into the body of a patient by injection into or through the skin of the patient, comprising:

a housing having a bottom surface adapted to be brought into contact with the skin of a patient, said bottom surface having a needle aperture therein;

a reservoir disposed within said housing for containing a liquid theraputic preparation;

a needle carrier disposed within said housing and movable between first and second positions within said housing, said movement occurring in a horizontal direction generally parallel to said bottom surface; and

an injection needle carried by said needle carrier for movement therewith, said injection needle having a first portion extending generally perpendicular to the bottom surface of said housing for penetrating the skin of the patient and a second portion extending generally parallel to the bottom surface of said housing for communicating with said reservoir;

wherein in said first position of said needle carrier said first portion of said injection needle is retracted within said housing and said second portion of said injection needle does not communicate with said reservoir, and in said second position of said needle carrier said first portion of said injection needle projects through said needle aperture and said second portion of said injection needle communicates with said reservoir, whereby movement of said needle carrier between said first and second positions causes said injection needle to penetrate the skin of the patient and said liquid theraputic preparation to begin to flow through said injection needle into the body of the patient.

2. A device as claimed in claim **1**, further comprising a resilient actuator for causing said first portion of said injection needle to project through said needle aperture when said needle carries is moved from said first position to said second position.

3. A device as claimed in claim **2**, wherein said resilient actuator comprises a resiliently deflectable portion of said needle carrier, said resiliently deflectable portion being held in an upper position when said needle carrier is in said first position and being allowed to resiliently return to a lower position when said needle carrier is moved to said second position.

4. A device as claimed in claim **3**, wherein said needle carrier includes a guide portion to which said deflectable portion is attached and said housing includes a guide track for allowing said guide portion and said deflectable portion to move in said horizontal direction while restraining vertical movement of said guide portion, said housing further comprising a fixed abutment for maintaining said deflectable portion in said upper position when said needle carrier is in said first position.

5. A device is claimed in claim **1**, wherein said needle carrier includes a manually operable slide button for moving said needle carrier between said first and second positions, said slide button being accessible through an opening in a top surface of said housing.

6. A device as claimed in claim **1**, wherein said reservoir is resiliently expandable in order to exert pressure on a liquid theraputic preparation contained therein, whereby said liquid theraputic preparation is automatically discharged from said reservoir when said second portion of said injection needle communicates with said reservoir.

7. A device as claimed in claim **6**, further comprising a flow regulator disposed in the flow path of said liquid theraputic preparation for causing said liquid theraputic preparation to be discharged from said reservoir at a controlled rate.

8. A device as claimed in claim **7**, wherein said flow regulator comprises as fixed flow resistor.

9. A device as claimed in claim **7**, wherein said flow regulator comprises a controllable valve.

10. A device as claimed in claim **6**, wherein said reservoir includes a self-sealing fill port for allowing said liquid theraputic preparation to be introduced into said reservoir under pressure.

11. A device as claimed in claim **1**, wherein said housing includes an opening for allowing said reservoir to be installed in said housing after said device is assembled.

12. A device as claimed in claim **1**, further comprising an adhesive layer in the bottom surface of said housing for adhering said device to the skin of a patient.

13. A device as claimed in claim **12**, further comprising a removable release liner for covering said adhesive layer and said needle aperture.

14. A device for delivering a liquid theraputic preparation into the body of a patient by injection into or through the skin, comprising:

a low-profile housing having a bottom surface adapted to be brought into contact with the skin of a patient, said bottom surface having a needle aperture therein, said housing being sufficiently low in height to allow said device to be worn inconspicuously under the clothing of the patent;

a reservoir disposed within said housing for containing a liquid theraputic preparation;

an injection needle disposed generally horizontally in said housing and adapted to communicate with said reservoir, said injection needle having a bent injection end adapted to project through said needle aperture; and

a movable needle carrier disposed in said housing for carrying said injection needle and for causing the injection end of said needle to project through said needle aperture upon movement of said needle carrier;

wherein said needle carrier and said injection needle are disposed in a side-by-side relationship with said reservoir in said housing in order to minimize the height of said housing above said bottom surface.

15. A device as claimed in claim **14**, wherein said injection end of said injection needle is bent at an angle of about 90° with respect to the horizontally extending portion of said injection needle.

16. A device as claimed in claim **14**, wherein said reservoir is held at a fixed position within said housing.

17. A device as claimed in claim **14**, wherein said reservoir is resiliently expandable in order to exert pressure on a liquid theraputic preparation contained therein, whereby said liquid theraputic preparation is automatically discharged from said reservoir.

18. A device for delivering a liquid theraputic preparation into the body of a patient by injection into or through the skin of the patient comprising:

a housing adapted to be held in contact with the skin of a patient;

a reservoir disposed within said housing for containing a liquid theraputic preparation, said reservoir including a Belleville spring which exerts pressure on said liquid theraputic preparation to discharge said liquid theraputic preparation from said reservoir at a relatively constant rate; and

an injection needle adapted to communicate with said reservoir and to project from said housing in order to inject said liquid theraputic preparation into or through the skin of the patient.

19. A device as claimed in claim **18**, wherein said reservoir includes a self-sealing fill port for allowing said liquid theraputic preparation to be introduced into said reservoir under pressure.

20. A device as claimed in claim **18**, further comprising a flow regulator disposed in the flow path of said liquid theraputic preparation to cause said liquid theraputic preparation be discharged from said reservoir at a controlled rate, said flow regulator being selected from the group consisting of a fixed flow resistor and a controllable valve.

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